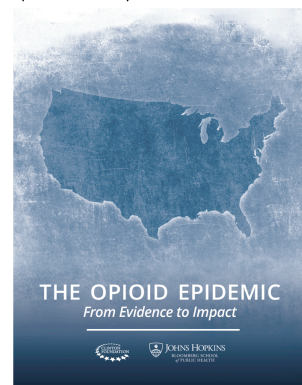


G. CALEB ALEXANDER, MD, MS, EXPERT WITNESS REPORT

BACKGROUND AND QUALIFICATIONS OF AUTHOR

1. My name is G. Caleb Alexander. I am a practicing general internist and Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health. I have been retained by the Multidistrict Litigation (MDL) to provide my scientific expertise regarding the opioid epidemic, nationally and in Cuyahoga and Summit Counties, and ways to abate or reduce the harms caused by the oversupply of opioids into these communities. My research focuses on the utilization, safety, effectiveness and regulation of prescription drugs.
2. As a physician, I am responsible for the primary care of approximately 250 patients, most of whom live in and around Baltimore County. I have clinic one half-day per week and I am also responsible for patient care matters that arise at other times. The patients that I see range from young adults to nonagenarians and as a primary care physician, I oversee their acute, preventive and chronic needs, which include conditions such as asthma, diabetes, hypertension, osteoporosis, chronic pain, anxiety and depression. While I do not specialize in the care of patients with opioid use disorder (OUD), I have patients in my practice with OUD who I co-manage with addiction specialists, and I care for patients who have lost family members from fatal opioid overdoses.
3. In contrast to my work as a physician, as a pharmacoepidemiologist, I focus on “the study of the uses and effects of drugs in well-defined populations.”¹ Pharmacoepidemiology is a bridge discipline that combines insights and tools from clinical medicine, pharmacology and epidemiology to generate fundamental new knowledge regarding the utilization, safety and effectiveness of prescription drugs. It also concerns itself with understanding the effects of pharmaceutical policy, such as regulatory or payment policies that influence prescription drug use. As a pharmacoepidemiologist, much of my work has focused on the nature, quality and determinants of prescription drug utilization in the United States, although I have also conducted or participated in many investigations examining the safety of specific products. I have used many different data for this work, often data that has already been assembled for other purposes, such as administrative claims data from health plans or large national surveys.
4. During the past eight years, I have devoted much of my professional time to addressing the opioid epidemic. I have served as one of three Co-Editors of monographs issued by the Johns Hopkins Bloomberg School of Public Health providing comprehensive, concrete, evidence-based solutions to the epidemic. These monographs were issued in October 2015 and October 2017; the latter report is provided as Appendix A (Figure 1). I have also testified in front of the U.S. Senate (March 2015) and the U.S. House of Representatives (November 2017);

Figure 1. Report on Opioid Epidemic (October 2017).



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briefed groups such as the National Governors Association, Congressional Black Caucus, Centers for Medicare and Medicaid Services and the National Academy of Science, Engineering and Medicine; and participated in efforts to improve the safe use of prescription opioids within Johns Hopkins Medicine and other health systems. My work focused on the epidemic has been funded by the Department of Health and Human Services Assistant Secretary for Planning and Evaluation (DHHS/ASPE), the Centers for Disease Control and Prevention (CDC), the Robert Wood Johnson Foundation and the National Institutes of Health (NIH).

5. I have published extensively about opioids, including analyses of prescription opioid use in the United States^{2,3} as well as evaluations of the structure and impact of regulatory^{4,5,6,7,8,9,10,11,12} and payment^{13,14,15,16} policies on opioid prescribing, dispensing and utilization. I have also co-authored policy perspectives^{17,18} and a widely referenced public health review of the epidemic.¹⁹
6. In addition to these studies, I have also led or participated in teams examining many other facets of the crisis, including: opioid initiation among members of households with a prescription opioid user;²⁰ the effect of reformulated Oxycontin on opioid utilization;²¹ physicians' knowledge and attitudes regarding non-medical opioid use;²² use of medication for opioid use disorder (MOUD);^{23,24} the costs and healthcare utilization associated with high-risk opioid use;²⁵ use of automated algorithms to identify non-medical opioid use;²⁶ the relationship between high-risk patients receiving prescription opioids and high-volume prescribers;²⁷ opioid use among individuals with HIV,²⁸ chronic kidney disease^{29,30} or recent surgery;^{31,32,33} and potential financial conflicts of interest among organizations opposed to the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain.^{34,35}
7. The studies I have performed have used a variety of epidemiologic methods, including: descriptive analyses based on cross-sectional, serial cross-sectional and period prevalence designs; retrospective cohort studies using difference-in-difference, interrupted time-series, comparative interrupted time-series and time-to-event designs; prospective cohort studies; qualitative assessments using grounded theory; and narrative and systematic reviews. A complete list of my publications is contained in my curriculum vitae (Appendix B).
8. I received a B.A. cum laude from the University of Pennsylvania (Philosophy) in 1993, an M.D. from Case Western Reserve University in 1998, and an M.S. from the University of Chicago in 2003. A more complete description of my qualifications is found in my curriculum vitae. My rate of compensation for this matter is \$700 per hour. I am also reimbursed for my out-of-pocket expenses. I am not compensated based on the outcome of this matter nor the substance of my report.
9. The opinions and conclusions in this report are based on the information and documentation that was available to me at this time, and they are my own, rather than those of Johns Hopkins University. I reserve the right to supplement and revise these perspectives based on additional evidence or information that is made available to me after the date of this report.

DATA SOURCES, METHODOLOGY AND OPINIONS

10. In preparing this report, I travelled to Akron, Ohio to meet with local stakeholders and reviewed materials from a number of sources, including: select confidential materials provided to me by Plaintiffs; published reports regarding the epidemic in Cuyahoga and Summit Counties such as the 2016 Cuyahoga County Opiate Task Force Report,³⁶ February 2019 Medical Examiner's Office Report from Cuyahoga County³⁷ and the 2017-2018 Summit County Opiate Task Force Strategic Plan;³⁸ information derived from other national and local experts submitting reports in this litigation; and peer-reviewed literature, whitepapers, reports from public health authorities, non-profit organizations and other publicly available sources. Many of my findings are based on prior investigations that my team and I have either performed or synthesized, such as knowledge contained in Appendix A and in citations such as references #1-#35. A complete list of the documents I consulted in preparing this report is provided as an Attachment.
11. For some remedies, such as the use of MOUD¹, the evidence-base is vast, with thousands of peer-reviewed manuscripts examining this matter. In these settings, formal evidence syntheses were often available, typically systematic reviews that represent a pre-specified, transparent, reproducible, highly structured approach to curating and critically appraising the totality of information required to address a carefully specified question. Because of their comprehensiveness and rigor, such evidence-syntheses are often regarded as at the top of the "evidence pyramid".³⁹ In some cases, I also used information available from authoritative sources such as the CDC, National Institutes on Drug Abuse (NIDA) or the Substance Abuse and Mental Health Services Administration (SAMHSA).
12. Whether or not systematic reviews were available, I reviewed the literature in order to learn more about the evidence supporting various approaches. There are a number of qualitative criteria that are often useful in evaluating the strength of scientific evidence supporting a given scientific finding or claim. These include factors such as the publishing journal, authorship team, affiliated institutions, funding source(s), data source(s), methodologic approach and interpretation.² The "Hill Criteria" (strength of association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy) are also an important means of evaluating the strength of causal inference possible from a given scientific study.⁴⁰
13. To estimate national abatement costs as described in Paragraphs #175-#181, I used an economic model of the opioid epidemic ("Markov model"). The model describes the dynamic movement of populations through different phases of the opioid epidemic, such as medical use, non-medical opioid use, OUD, overdose and death. It is based on publicly

¹ Definitions of terms such as "opioid use disorder", "addiction", "non-medical opioid use" and "misuse" are provided in Dr. Katherine Keyes' expert report.

² Neither these criteria nor the Hill Criteria are absolute. Rather, they serve as contextual factors that provide qualitative information that can be useful in examining the credibility of scientific claims.

available data from the United States Census Bureau, Centers for Disease Control and Prevention (CDC), National Survey on Drug Use and Health (NSDUH), National Health and Nutrition Examination Survey (NHANES), and National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), as well as information derived from the peer-reviewed literature and other models of the opioid epidemic.^{41,42,43} While no model can perfectly capture all of the dynamic and complex processes of the epidemic, developing and analyzing formal models forces one to make assumptions explicit, and allows for these assumptions to be evaluated in light of the best available data. Such models provide policy-makers with information about the potential public health value of different interventions, and they allow for estimations of the costs of interventions such as those provided later in this report.

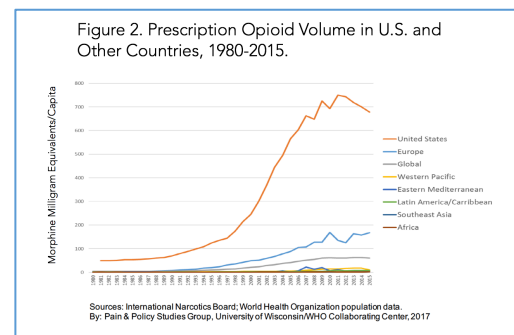
14. There is widespread consensus in both clinical and public health communities that the abatement measures identified in this report are effective in reversing opioid-related morbidity and mortality. The measures discussed herein have been put forth by numerous consensus panels, task forces, professional society organizations and others. Disagreement about these solutions, when present, has tended to focus more on the priority of the interventions given limited funding (e.g., how much should be spent on law enforcement vs. MOUD)⁴⁴, as well as in some cases, the potential unintended effects of some interventions. Fortunately, there is a large evidence base to guide the selection of interventions that should be undertaken, and also a recognition of the critical point, as expressed by former Congressman John Delaney, "that the cost of doing nothing is not nothing".⁴⁵
15. I conclude that an opioid epidemic currently exists in Cuyahoga and Summit Counties. This epidemic continues to result in high levels of opioid-related morbidity and mortality as described in this report and that of other experts such as Katherine Keyes. I further conclude that based on my experience in epidemiology, clinical medicine and public health, my extensive application of these fields to the opioid epidemic, and my analysis in this case, I am able to determine what additional evidence-based and evidence-informed measures and approaches should be used in Cuyahoga and Summit Counties to reduce opioid-related morbidity and mortality. These measures and approaches are described below. The specific utilization and combination of measures should be subject to the opinions of other experts, especially within the affected communities. The opinions expressed by me in this report are held by me to a reasonable degree of professional certainty.

INDICIA OF OPIOID CRISIS

16. The modern opioid epidemic can be traced to the 1980's, when a growing number of journal articles argued that the perceived risks of opioids were overstated and that more aggressive pain management was needed in the United States.^{46,47,48} One often cited report, published in 1980 in the New England Journal of Medicine and entitled "*Addiction Rare in Patients Treated With Narcotics*",⁴⁹ is a particularly striking example of the misapplication of scientific evidence regarding the risks of opioids and a cautionary tale of how such information has been perpetuated over time.⁵⁰ While opioid sales increased gradually through the early 1990's, in 1996, the FDA approved an extended-release/long-acting formulation of

oxycodone, and sales accelerated, fuelled in part by aggressive marketing and promotion⁵¹ as well as the activities of a number of intermediary organizations supported by manufacturers.^{3,52,53} As a result, between 1992 and 2010, the volume of opioids prescribed in the United States increased by ~400 percent.⁵⁴ Rates of addiction, overdose deaths, and many other opioid-related harms increased in parallel with rising sales.⁵⁵ In 2012, health care providers wrote 259 million prescriptions for opioid or narcotic pain relievers - enough prescriptions for every adult American to have a bottle of pills.⁵⁶

17. The current opioid epidemic is the worst drug epidemic in our nation's history. Prescription opioids play a vital role in the treatment of severe, acute pain and pain at the end of life, yet the oversupply of opioids in other settings has skyrocketed.^{57,58} In 2017, an estimated 47,600 people died in the United States (US) from opioids, more than from motor vehicle accidents, suicide, gun violence, or than died at the peak of the AIDS epidemic.⁵⁹ For the third year in a row, life expectancy in the United States has declined.⁶⁰ For every life that has been lost, countless others have been affected by opioid use disorder or other collateral harms. Despite modest declines in opioid use since 2010, they remain vastly overused, both relative to pre-epidemic baseline as well as to other parts of the world (Figure 2). This overuse is a key driver of ongoing injuries and deaths from the epidemic.



18. The National Survey on Drug Use and Health (NSDUH) suggests that, in 2015, 91.8 million – that is, more than one-third of U.S. civilian, non-institutionalized adults – used prescription opioids. Based on these data, another 11.5 million (4.7%) reported misusing opioids and 1.9 million (0.8%) fulfilled formal diagnostic criteria for an opioid use disorder (OUD), or addiction, within the past year.⁶¹ This substantially underestimates the number of Americans with opioid addiction, since it does not include individuals who may be stably maintained on medication assisted treatment (MAT) nor those with a history of OUD whose symptoms are no longer prominent; it also excludes individuals who are homeless, incarcerated or otherwise institutionalized. Based on data from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), as many as ~2.5-3.0 million additional Americans may fulfil criteria for lifetime diagnosis of opioid use disorder.⁶²

19. Between 1999 to 2017, more than 700,000 individuals died from a drug overdose of any type in the United States.⁶³ During the past decade, the epidemic has been further complicated by an abrupt rise in heroin-related overdoses and overdoses from synthetic opioids such as illicitly manufactured fentanyl. There is a clear link between non-medical use of prescription

³ For example, manufacturers provided financial support to professional societies such as the American Pain Society, advocacy groups, the Federation of State Medical Boards and other organizations, who in turn developed programs, position statements and other materials arguing for more aggressive pain management, including the use of opioids.

opioids and subsequent heroin or illicit fentanyl use, with several studies suggesting that as many as 70-80% of current heroin users reporting prior non-medical prescription opioid use before initiating heroin.⁶⁴ In 2017, overdose deaths involving opioids – both prescription and illicit – were six times higher than in 1999.⁶⁵

20. In addition to the human suffering and loss of life, the epidemic poses enormous economic costs. Florence et al. estimated the 2013 costs of the epidemic at \$78.5 billion, including ~\$21.5 billion for fatality costs and ~\$57 billion for non-fatality costs.⁶⁶ More recently, in 2017, U.S. Council of Economic Advisers (CEA) estimated the 2015 costs of the epidemic at \$504 billion, or 2.8% of the Gross Domestic Product (GDP).⁶⁷ These estimated costs included ~\$432 billion for fatality costs and ~\$72 billion for non-fatality costs. The difference between Florence and the CEA estimates are driven by growth in the epidemic and fatality costs, and note that these are annual costs; the 10-year present value of costs range from \$682 billion to \$4.3 trillion.⁴
21. In Ohio, the opioid crisis has been particularly acute, including in Cuyahoga and Summit Counties. There was a 41% increase in overdose mortality in Cuyahoga County from 2006 to 2014, including a four-fold increase in heroin-related deaths (49 deaths in 2006 to 198 deaths in 2014).⁶⁸ In 2017, the number of fatal opioid overdoses in Ohio, 4,293, exceeded those of any other state,⁶⁹ while in Cuyahoga County, fatal overdoses reached a record-high of 727 deaths.⁷⁰ Fentanyl-associated deaths have also soared, from 37 deaths in 2014 to 492 deaths in 2017.^{71,72} In Summit County, mortality from drug overdoses in 2015 and 2016 (480) was equivalent to the entire decade before, from 2000-2009 (474)⁷³, with fentanyl as the most commonly identified cause of death amongst drug-related deaths in 2015, followed by morphine and heroin.⁷⁴ At the height of the epidemic in July 2016, there were as many as 19 total drug overdoses in emergency rooms per day in Summit County⁷⁵, up from an average of ~2.5 overdose emergency room visits per day in 2012-2015.⁷⁶
22. Cuyahoga County and Summit County have made great strides to address the epidemic, and the counties continue to invest heavily to abate the crisis. The Cuyahoga County Opiate Task Force (CCOTF), formed in 2010, has grown since its inception and is composed of nearly 200 individuals working in tandem across 65 member organizations representing public health officials, law enforcement, health care providers, physicians, pharmacists, drug treatment and recovery services, mental health services, educators, concerned citizens, and individuals in recovery.⁷⁷ In 2016, the CCOTF's activities included the launch of a three-month Heroin/Fentanyl Prevention Awareness Campaign, increased naloxone distribution through local pharmacies and law enforcement, and increased funding for MOUD, particularly for drug court participants.^{78,79} The CCOTF also worked with law enforcement to establish 30 permanent medication drop boxes and participated in designated drug takeback days, collecting more than 100,000 pounds of expired medication. Since then, it has also helped

⁴ Ten-year present value costs based on applying "present value of annuity" formula with a 3% discount rate. Formula available at: http://financeformulas.net/Present_Value_of_Annuity.html

facilitate evidence-based education on prescription drug misuse/abuse for more than 2,000 middle and high school students. It has also created a mandated physician education module that covers use of the state's Prescription Drug Monitoring Program (PDMP), screening tools, and prescribing guidelines. During the past three years the Summit County Opiate Task Force (SCOTF) has similarly invested in addressing the epidemic, such as by increasing the availability and training in the use of naloxone among law enforcement, expanding residential treatment and detox capacity and establishing a Summit County Safe Needle Exchange as well as a drug testing program.^{80,81,82} The SCOTF has also partnered with pharmacies, emergency medical services, and hospitals to distribute more than 60,000 prescription drug disposal pouches, and has helped significantly expand the County's detox center.^{83,84} Quick Response Teams visit residents within seven days of an overdose to connect them to treatment services and to provide naloxone training to friends and family.⁸⁵

23. Data from 2018 suggest some gains. For example, in Cuyahoga County, from 2017 to 2018 overdose deaths related to fentanyl and heroin are estimated to have dropped from 492 to 404 and 240 to 153, respectively.⁸⁶ In Summit County, total overdose deaths declined from 310 in 2016 to 105 in 2018⁸⁷, and overdose-related Emergency Department visits in the County have declined from an average of ~6.5 per day in 2016-2017⁸⁸ to an average of 3.0 overdoses per day in October 2018⁸⁹ and 3.8 overdoses per day in January-February 2019.⁹⁰
24. Despite these investments, which have helped to a degree, many more resources will be needed to fully abate injuries and deaths in Cuyahoga and Summit Counties, as demonstrated by continued evidence of substantial harms and a continuing epidemic. I have noted the need for these in my visit to Akron and review of materials to prepare this report, and these needs are also referenced in Katherine Keyes' expert report. For example, based on my assessment of materials in preparation for this report: rates of overdose remain high;^{91,92} children are being adversely effected because of drug exposure, death of parents, and other trauma;^{93,94} neonatal abstinence syndrome has increased;⁹⁵ resources are stretched;⁹⁶ treatment remains in short supply;⁹⁷ and a lack of coordination further prevents people who need treatment being connected to the services that can deliver it. Similarly, as noted by the Cuyahoga County's Medical Examiner Thomas Gilson during a January 2019 interview, "We are by no means back to where we were before the crisis started and these [2018] numbers, while encouraging, really indicate we need to strenuously continue our efforts."⁹⁸
25. Though the current opioid epidemic is the worst drug epidemic in our nation's history, it is not the first opioid crisis we have had.⁹⁹ In mid- to late-19th century, opioid use rose dramatically, fuelled by unrestrained prescribing and liberal use of opioids to treat Civil War combatants and veterans.¹⁰⁰ Historical precedent suggests that the current crisis can be successfully reversed with a multi-faceted approach that addresses the root causes of the epidemic, including misleading marketing and promotion and widespread overprescribing, while also investing in treatment and recovery.¹⁰¹ Further investing in law enforcement is also important. My report presents key, evidence-based recommendations that should be implemented to abate the opioid epidemic by both minimizing further unnecessary exposure to opioids and addressing the harms that have already been caused.

PROBLEM CAN BE SOLVED

26. Despite the unprecedented injuries and deaths from the opioid epidemic, there is virtual consensus in the clinical, public health and health policy communities that the epidemic can be abated. This consensus is reflected in the high concordance between a November 2017 report from the current Administration regarding the opioid epidemic,¹⁰² a report that I co-Edited released by the Johns Hopkins Bloomberg School of Public Health,¹⁰³ and other groups' recommendations to prevent further harms.^{104,105,106}

27. Our prior work as described in Appendix A stemmed from three principles (Figure 3) that provide a valuable basis for current efforts. The first principle is informing action with evidence. Fortunately, there is a large and ever-expanding evidence-base regarding many facets of the opioid epidemic. For example, there is clear scientific consensus that: (1) opioids have an unfavorable risk/benefit balance for many patients who have received them;¹⁰⁷ (2) non-medical opioid use and addiction are not uncommon;¹⁰⁸ (3) the risks of overdose are dependent on dose and duration of opioid use;^{109,110,111} and (4) medications for opioid use disorder are safe and effective and represent a cornerstone of OUD treatment.¹¹²

Figure 3. Principles Governing Johns Hopkins Report: "The Opioid Epidemic: From Evidence to Impact".

- **Informing Action with Evidence**
 - Scaling up evidence-based interventions; rapidly implementing and evaluating promising policies and programs
- **Intervening Comprehensively**
 - All along supply chain; clinic, community and addiction treatment settings; primary, secondary and tertiary prevention; creating synergies across different interventions
- **Promoting appropriate & safe opioid use**
 - Reducing overuse; focus on safe use, storage and disposal; optimizing use in accordance with best practices

28. The second principle is intervening comprehensively. The epidemic is a complex one because it involves many stakeholders and harm accrues at many levels. Because of this, interventions are needed all along the supply chain, from opioid manufacturers to wholesalers to pharmacies, health systems, hospitals, prescribers and the end users of prescription opioids, patients. In addition to reducing the overuse of prescription opioids in clinical practice, efforts are also needed to identify and treat those misusing opioids or affected by opioid use disorder, including to identify important treatment gaps that exist, to prevent overdoses and to institute harm reduction programs. When it comes to abatement, there are many other important partners beyond the health care system, including those working within law enforcement, criminal justice, educational systems and the courts.

29. The third principle is improving the care of those with pain. Improving quality of care for people in pain is not threatened by reducing opioid overuse, it demands it. Millions of American experience chronic, non-cancer pain, and efforts to reduce the overuse of prescription opioids offer an important opportunity to improve their quality of care. While there is a significant need for new pain treatments, an increasing body of evidence also underscores principles of high-quality pain management, including the importance of assessing pain comprehensively, recognizing that it is a multidimensional concept, and focusing on physical, psychological and social functioning rather than pain levels per se.

30. Some abatement approaches may be framed in the context of looking forward five or ten years.⁵ However, the legacy of the opioid epidemic will endure far beyond that. Prevention of new cases of addiction will require long-term investments in research and training to transform the culture of pain treatment in America. While opioid use disorder can be treated and may remit, it is not curable, and some individuals with opioid use disorder will require treatment indefinitely.^{113,114,115} Others have acquired HIV or other Hepatitis C from an addiction that began with prescription opioids,^{116,117} and they may require indefinite care for these comorbid conditions. Foster care for those orphaned by the epidemic, child protective services, and services for children impacted by opioid use in utero must be resourced to address the needs of children and young adults as they grow and develop. For many, living healthy, productive lives in recovery is an active process, and thus to be successful, individuals must be supported with long-term resources to maximize their opportunities for success.

MISCONCEPTIONS MUST BE ADDRESSED

31. In order to address and abate the epidemic, it is also important to eliminate common misconceptions about opioids and the ensuing epidemic, since inaccurate, misleading or false statements about the epidemic have allowed it to flourish. For example, during the first decade of the epidemic, some said that if a patient has “organic” pain, one need not worry about the addictive potential of opioids. I was taught this as a resident in Internal Medicine at the University of Pennsylvania in the late 1990’s, and I was part of an entire generation of health care professionals who were not properly trained on this point. This approach led me, and my fellow physicians, to prescribe opioids much more liberally than we might have otherwise for patients who had a clear source of their pain (e.g., broken bone, cancer, recent surgery, inpatient procedure), viewing these patients as “legitimate pain patients”⁶, while overlooking the paucity of evidence that the source of a patient’s pain protects them from developing an opioid use disorder or other adverse event.

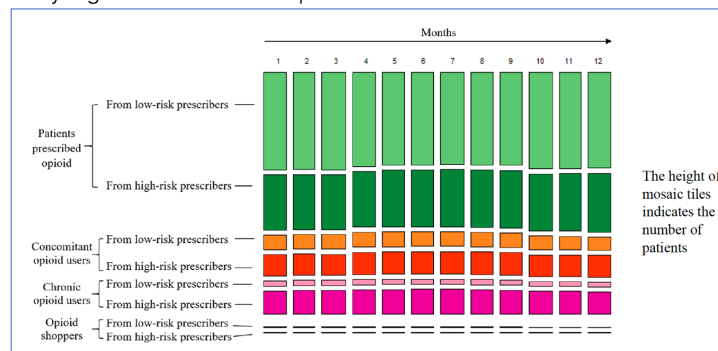
32. Another misconception that is important to understand and correct is that the primary driver of the epidemic is one of abuse, rather than addiction.¹¹⁸ (Dependence is distinct from both of these and discussed further in Paragraph #51). This has been one of the most destructive and widely circulated misconceptions about the epidemic, because it has been used to argue for a reliance on ineffective solutions (e.g., risk mitigation measures such as patient contracts or unscheduled pill counts) while allowing for the crisis to flourish. Abuse is a behavior. Addiction is a brain disease and not one that is simply a function of “bad choices”.¹¹⁹ It requires different approaches to support prevention, treatment and recovery as discussed herein.

⁵ This medium-term view strikes a balance – it is long enough to support infrastructure development and several cycles of planning and evaluation while avoiding some of the uncertainty entailed in trying to anticipate the magnitude of sequelae from the epidemic that may last decades or even generations.

⁶ The notion of a “legitimate pain patient” also reinforces stigma against those with non-medical opioid use or addiction who commonly have pain, suggesting that pain that they experience is not “legitimate”.

33. A related misconception is that the epidemic is largely driven by devious individuals such as rogue physicians and patients who are “doctor-shoppers”. Such a frame has fostered a narrow focus on individual “bad-actors” that distracts from the much more pervasive, insidious and systematic drivers of the epidemic.⁷ In other words, individuals such as “doctor-

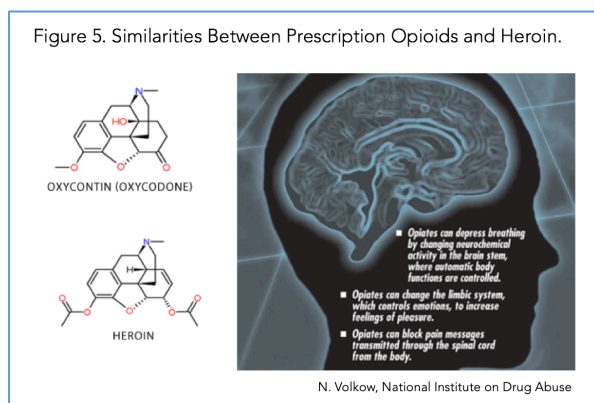
Figure 4. Opioid Shoppers Dwarfed By Other High Risk Patient Groups, Many High Risk Patients Get Opioids from Low-Volume Prescribers



Chang et al. Addiction. 2017.

represent a very small proportion of people who are at high risk for opioid-related adverse events, and they also account for a small proportion of prescription opioids entering the general circulation. For example, consider Figure 4, which is derived from a database study that my co-authors and I performed and which depicts three groups of high risk opioid users on a monthly basis: those using chronic high dose opioids, those using opioids combined with benzodiazepines, and opioid shoppers.¹²⁰ Note that the number of opioid shoppers is dwarfed by the other groups of high risk users.⁸ It is important that “doctor-shopper” patients and rogue prescribers are identified and targeted, but such efforts must not come at the expense of fundamental changes in prescribing and OUD identification and treatment in the U.S.

34. Some have also argued that if we constrain access to prescription opioids, it will just push people to heroin. It is important to understand the relationship between the prescription opioid epidemic and heroin/illicit fentanyl use.¹²¹ The heroin and (illicit) fentanyl epidemic has



flourished because of the prescription opioid epidemic. Prescription opioids and heroin/illicit fentanyl are remarkably similar in their organic structure (Figure 5), pharmacokinetics (what the body does to the drug) and pharmacodynamics (what the drug does to the body). In contrast to 40 years ago, today most individuals who use heroin/illicit fentanyl report that prescription opioids were their first opioids of use.¹²² While some individuals do initiate heroin

⁷ In addition, an emphasis on “opioid shoppers” as the root cause of the epidemic also supports a simplistic and erroneous notion that as long as one is a “legitimate pain patient”, the risks of opioids are overblown.

⁸ The Figure also demonstrates that a significant proportion of each group of high-risk patients receives prescription opioids from low-volume prescribers, indicating the importance of training and provider education across a continuum of prescribers.

without having first used prescription opioids, the vast majority do not. There is not a zero-sum game between efforts to reduce the oversupply of prescription opioids and efforts to reduce heroin/illicit fentanyl use. However, it is vital that comprehensive interventions take place so that as the oversupply of prescription opioids is reduced, individuals do *not* transition to heroin or illicit fentanyl and treatment for opioid misuse and OUD is available to all in need.

MOVING FROM A NATIONAL TO A COMMUNITY FOCUS

35. The opioid epidemic has impacted communities differently. Because of this, there is not a one-size-fits-all approach with respect to the abatement remedies. For example, some communities have been ravaged by fentanyl, while others have not. In some communities, large investments have been made to reduce the oversupply of prescription opioids, while in other communities, this remains a pressing matter. Some communities have invested heavily in naloxone distribution and training, others have struggled to identify the resources for such programs. Because of this variation, while each of the remedies are worthy of consideration, some will be far more important than others in specific communities, and stakeholders should be consulted as abatement remedies are iteratively designed, deployed and evaluated at local levels.⁹ These stakeholders include, but are not limited to, public health and law enforcement; treatment providers and systems; behavioral health providers and systems; educators; community advocates; employers; payers; and the courts.
36. The foundation of any community's response should be a comprehensive needs assessment, which is based on a systematic approach for reviewing the public health needs faced by a population. Such an assessment enables community leaders to objectively determine the key public health issues in local populations, and provides a better understanding of how to prioritize and allocate resources in order to efficiently address these issues.^{123,124} Public health needs assessments may use a combination of epidemiologic, qualitative and comparative methods to incorporate clinical, ethical and economic considerations when determining solutions, i.e. "what should be done, what can be done, and what can be afforded."¹²⁵ Furthermore, needs assessments are not only intended to measure ill health, but also to incorporate the concept of "capacity to benefit" in order to place emphasis on interventions producing tangible benefits to specific community populations.
37. There are many frameworks that can be used to conduct a needs assessment and several tools are available to guide their development and implementation.^{126,127,128} Regardless of the framework that is selected, assessment can be broadly separated into six main steps.^{129,130,131}
 - 1) Scoping the needs assessment: Defining population to be studied, identifying assessment objectives and understanding resources available to support it.

⁹ Although nearly all of the remedies discussed herein are directly relevant to Cuyahoga and Summit counties, a few, such as the need for greater investment in the research infrastructure to identify new treatments for pain and OUD, are primarily relevant at federal rather than state or local levels.

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- 2) Defining stakeholders, community leaders and sources of information: Articulating relevant participants, reviewing existing data sources (e.g., PDMP, task force reports) and developing and implementing strategies to fill gaps in existing sources.
 - 3) Identifying health needs: Using information sourced from prior step, characterizing the health needs of the community, while ensuring those of different subpopulations are appropriately identified.
 - 4) Establishing opportunities and strategies to address needs: Identifying and prioritizing evidence-based and evidence-informed strategies to address needs, taking into account limitations and cost-effectiveness, where available.¹⁰
 - 5) Creating community action plan: Taking into consideration the resources available, develop plans that contain specific, measurable, attainable, realistic and timely (SMART) objectives.^{132,133}
 - 6) Evaluating progress: Assessing baseline measures, identifying success metrics, gathering credible evidence, and communicating results to stakeholders and community leaders, while iteratively adjusting strategies to reflect findings of evaluations.
38. Both Cuyahoga and Summit Counties have already conducted many laudable activities to lay the groundwork for a comprehensive needs assessment. For example, Summit County's Cross-System Sequential Intercept Mapping project, implemented by the County's Criminal Justice Coordinating Center of Excellence, represents a dynamic approach aimed at creating effective systems of care bridging criminal justice and mental health services at specific "intercepts" (i.e. specific stages in the continuum of the criminal justice system).¹³⁴ The objectives of the Mapping project were: to develop a comprehensive picture of how individuals with substance use disorders flow through Summit County's criminal justice system along six intercept points;¹¹ to identify gaps, resources and opportunities that can be provided to individuals at each intercept; and to develop and prioritize activities that can improve system and service level responses for individuals in the target population. The project identified and prioritized specific recommendations at each intercept, information that can be integrated and synthesized in a comprehensive needs assessment that extends beyond the County's criminal justice and mental health services systems.

Figure 6. Example of Scale to Rank Strategies to Support Community Needs Assessment.

Time	Resources	Competing Priorities
1= Large amount of time needed to implement strategy	1= Large amount of resources needed to implement strategy	1= Large amount of competing priorities
2 = Substantial amount of time needed to implement strategy	2 = Substantial amount of resources needed to implement strategy	2 = Substantial amount of competing priorities
3 = Some amount of time needed to implement strategy	3 = Some amount of resources needed to implement strategy	3 = Some competing priorities
4 = A little amount of time needed to implement strategy	4 = A little amount of resources needed to implement strategy	4 = A few competing priorities
5 = Very little amount of time needed to implement strategy	5 = Very little amount of resources needed to implement strategy	5 = No competing priorities

CDC. Community Needs Assessments (Table 10). 2013.

39. No single abatement remedy that is proposed can fully reverse the oversupply of opioids and associated morbidity and mortality; there are no magic bullets, and thus the importance of

¹⁰ Strategies should be prioritized given pre-identified criteria, such as size and severity of problem, current interventions and resources, economic and social impact, and magnitude of public health concern. For one example of how strategies can be ranked, please see Figure 6.

¹¹ These points included: prevention/treatment/regulation, first contact and emergency services, initial detention/court hearings, jails and courts, re-entry, and probation/community supervision.

intervening comprehensively as noted in Paragraph #28. Also, some of the abatement remedies discussed may interact with one another in synergistic fashion, and successful implementation of some strategies may be dependent upon the simultaneous intervention of other strategies. For example, initiatives to decrease stigma and educate law enforcement and other community members about addiction may increase the demand for treatment, while expansions in treatment capacity to meet such demand may decrease rates of active OUD, which in turn may decrease overdose deaths and the need for naloxone. The dynamic nature of the epidemic, as well as the potential for these sorts of interactions, speaks to the vital need for surveillance and leadership as outlined in Paragraphs #126-#136. This will maximize the ability of communities to respond effectively to near real-time intelligence regarding key parameters of the epidemic and thus to use, and redirect, resources to maximize their public health value.

ABATEMENT CATEGORIES

40. There are three major categories of remedies that must be undertaken to address the epidemic.^{12,13} First, we must improve the safe use of prescription opioids and treatment of pain, since opioid oversupply has been a key driver of the epidemic.^{135,136} Second, we must identify and treat individuals with opioid use disorder. This is important because even if prescription opioids were to be responsibly marketed, promoted and used beginning tomorrow, there are still several million Americans with opioid use disorder, many of whom require active treatment and all of whom deserve access to care if and when treatment or recovery services are sought. Third, we must customize abatement remedies for specific subpopulations, including: individuals within the criminal justice system, children, adolescents, and young adults; child in foster care and protective services; pregnant women and neonates; and African Americans, American Indians and Alaskan Natives (AIANs). We must also address the large number of individuals who may misuse opioids but who do not yet not fulfil formal criteria for an opioid use disorder. While I outline a comprehensive set of abatement remedies, as well as consider some contextual factors relevant to their local application (e.g., Paragraphs #35-#39), significant progress can be made in abating this crisis through various elements and combinations of these elements. I leave the task of defining the specific application of these programs for Cuyahoga and Summit Counties to the communities themselves, with assistance where needed from experts participating in the MDL and other outside consultants.

¹² Other interventions are important in addressing the epidemic yet beyond the scope of this report, such as changes to coverage and reimbursement policies so as to improve options for pain treatment and reduce financial and non-financial barriers to treatments for opioid use disorder.

¹³ While there are other ways to classify potential remedies, the elements within these remedies are remarkably consistent across different proposals, reflecting the widespread consensus about what needs to be done.

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- Category 1: Reducing Opioid Oversupply and Improving Safe Opioid Use
 - 1A. Health Professional Education
 - 1B. Improving Pain Treatment
 - 1C. Prescription Drug Monitoring Programs & Clinical Decision Support
 - 1D. Patient and Public Education
 - 1E. Drug Disposal Guidelines and Programs
 - 1F. Expanding Scientific Knowledge
- Category 2: Identifying and Treating Individuals with Opioid Use Disorder
 - 2A. Treatment for Opioid Use Disorder
 - 2B. Peer Coaches, Recovery Housing and Jobs Training
 - 2C. Naloxone Distribution and Training
 - 2D. Harm Reduction Interventions
 - 2E. Surveillance and Leadership
- Category 3: Caring for Special Populations
 - 3A. Individuals Within Criminal Justice System
 - 3B. Children, Adolescents and Young Adults
 - 3C. Children in Foster Care and Child Protective Services
 - 3D. Pregnant Women and Neonates
 - 3E. African Americans, American Indians and Alaskan Natives
 - 3F. Individuals with Opioid Misuse

CATEGORY 1: REDUCING OPIOID OVERSUPPLY AND IMPROVING SAFE OPIOID USE

The goal of this category is to reduce the widespread oversupply of prescription opioids so as to decrease injuries and deaths from these products.¹⁴ This is important because the oversupply of prescription opioids during the past two decades has been an important driver of the opioid epidemic.¹⁵ Harm from this oversupply arises from many points in the continuum of care, ranging from how clinicians treat pain to the diversion of opioids throughout the supply chain.

CATEGORY 1A. HEALTH PROFESSIONAL EDUCATION

The goal of this remedy is to train health care providers, including prescribers and other health care personnel, such as dispensers (pharmacists) and emergency medical technicians (EMTs), regarding the appropriate use of opioids in clinical practice, as well as how to identify and appropriately respond to patients who may have an opioid use disorder. This is important because historically, many providers have overestimated the effectiveness of opioids and/or underestimated their risks. This has contributed to the oversupply of opioids, not only with

¹⁴ This report excludes consideration of Drug Enforcement Agency (DEA) quotas, controlled substance scheduling and other mechanisms federal government may use to reduce supply of opioids or precursors in the marketplace.

¹⁵ Reductions in opioid oversupply will also decrease opioid demand, since opioids are highly habit forming, tolerance quickly develops and a substantial minority of individuals receiving chronic opioids develop OUD.

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respect to whether they are used at all, but also with respect to the dose and duration of use. In addition, opioid use disorder is often not recognized in clinical practice, and even when recognized, the delivery of treatment and recovery services often falls short.

41. Many types of provider education should be performed, and this training should be customized to address the learning and professional development needs of different audiences. For example, medical, nursing and other health professional trainees should have comprehensive, longitudinal exposure to principles of pain management, the appropriate role of opioids, and the diagnosis and treatment of individuals with opioid use disorder. Graduate medical education programs, including internships, residencies and fellowships, should expand more advanced training in these areas, as well as facilitate the completion of waivers allowing for the prescription of buprenorphine for the treatment of OUD.^{137,138} Practicing clinicians, especially prescribers, should also have additional opportunities for continuing professional education through workshops and seminars, as well as through more applied clinical interventions such as audit and feedback and other reminder systems.¹³⁹
42. One of the most systematic and well-studied approaches at direct training of prescribers, sometimes referred to as “academic detailing”, should also be employed. Academic detailing is a method of evidence-based, interactive outreach to prescribers that uses trained personnel make face-to-face visits with clinicians to promote optimal prescribing and improve the quality of patient care. Established in the 1980’s, there are dozens of studies that provide evidence of its value^{140,141,142,143}, including a recent investigation indicating large decreases in opioid prescribing following a multi-level intervention that included academic detailing.¹⁴⁴ A systemic review of the impact of provider education, the most comprehensive assessment of its kind, concluded that this strategy results in significant improvements in prescribing quality¹⁴⁵, and is consistent with a large literature overview examining the effectiveness of interventions to shape prescriber behaviour.¹⁴⁶
43. Academic detailing should be considered for at least four types of health care providers:
 - Licensed prescribers, such as physicians, dentists, nurse practitioners and physicians’ assistants, are important to target because they issue prescriptions for opioids and other analgesics.
 - Nurses, especially in settings such as Emergency Departments, urgent care settings and other settings where opioids are commonly used, should be targeted because they are in an influential position to shape the culture of pain management and to raise awareness about evidence-based methods to identify and treat pain and opioid use disorder.
 - Dispensers, or pharmacists, should be targeted because they dispense opioids and are increasingly responsible for implementing drug utilization management policies and practices designed by payers and pharmacy benefits managers (PBMs).
 - Emergency medical technicians (EMT’s), are important to reach because they are often the first point of contact with individuals who have overdosed, and thus in a key position to bridge a common treatment gap that contributes to low rates of evidence-based treatment for OUD, namely, individuals who are resuscitated but not connected with OUD treatment.

44. Resources permitting, education of other health care personnel, such as pharmacy technicians and physical therapists, should also be undertaken. Since opioid oversupply, as well as opioid use disorder, are both so common, these personnel also regularly engage with patients who have a high likelihood of being harmed by the epidemic, and thus they too are in a position to support a required cultural shift in the paradigm of pain and opioid use disorder (OUD) identification and management in the United States.
45. While there are many criteria that could be used to select physicians who should be detailed, a conservative approach might focus on ~10% of all active, ambulatory patient-care physicians - those that account for the highest prescribed opioid volume.¹⁴⁶ Because opioid prescribing is highly skewed, such a focus, properly designed, could reach prescribers accounting for the majority of opioids in the marketplace. For example, we previously found that fewer than 5% of prescribers in Florida accounted for approximately two-fifths of opioid prescriptions and two-thirds of opioid volume during a given calendar year.¹⁴⁷ Similarly, a study of workers compensation claims in California indicated that approximately 87% of opioid volume was accounted for by the top 10% of prescribers.¹⁴⁸
46. Since academic detailing should target high volume prescribers, it must be based on information regarding specific individuals' prescribing behaviors. One source of such information would be states' Prescription Drug Monitoring Program (PDMP) data. As discussed in Paragraph #59, every state in the country now has a PDMP, and these programs compile and redistribute controlled substance prescribing information for clinical and law enforcement purposes. However, in many states, restrictions on access to PDMP data might prevent their use for this purpose and legislative efforts to broaden their availability would be uncertain and, at best, delayed.
47. An alternative source of similar data would be from a market intelligence firm such as Symphony Health or IQVIA. These companies license data regarding prescription drug prescribing to pharmaceutical companies and other clients, and in contrast to PDMPs, would represent a single source of more efficiently gathered, much better curated and more timely information regarding both physician and non-physician prescribers (e.g., advanced nurse practitioners, physicians' assistants).¹⁴⁹
48. The value of provider education lies in the quality of the information that is delivered. Thus, the information must be of the highest quality and from the most reputable sources. A natural foundation for this effort would be the 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, given the credibility of the CDC, the extraordinary rigor that was exercised in its development, as well as the widespread endorsement that it has received.¹⁵⁰ This Guideline could be cross-referenced with other guidelines and sources used by established provider education programs already underway

¹⁴⁶ While this discussion focuses on ambulatory care, an increasing number of evidence-based guidelines are also available for the post-surgical setting, where opioids have also been heavily oversupplied; an academic detailing program should also be considered for these prescribers as well.

on opioids.^{151,152} In addition to delivering information about best practices, academic detailing should also include reports so that individual prescribers or dispensing pharmacists can review and critically evaluate their prescribing or dispensing patterns relative to peers at local, regional and national levels, as well as identify instances of prescribing or dispensing that may warrant closer and more critical evaluation.

49. Provider education has to deliver a limited number of focused messages or it will not be effective. The CDC Guideline for Prescribing Opioids for Chronic Pain¹⁷ includes twelve scientifically supported "clinical reminders" that can be used as basis for provider education modules:

- 1) Opioids are not first-line or routine therapy for chronic pain;
- 2) Establish and measure goals for pain and function;
- 3) Discuss benefits and risks, as well as the availability of non-opioid therapies with patients;
- 4) Use immediate-release opioids when starting opioid therapy;
- 5) Start with the lowest effective dosage and use caution when titrating the dose (avoid increasing dosages by ≥ 90 morphine milligram equivalents/day);
- 6) When treating acute pain, prescribe quantities no greater than what is needed for the expected duration of pain that is severe enough to warrant opioids (often no more than 3 days);
- 7) Follow-up and re-evaluate risks and benefits with patients as they continue opioid therapy, and should the harms of continued opioid therapy outweigh the benefits, taper to a lower dosage or taper and discontinue opioid therapy;
- 8) Evaluate risk factors for opioid-related harms and incorporate risk mitigation strategies into treatment regimens;
- 9) Utilize PDMP data to determine whether a patient is receiving other therapies that put them at risk;
- 10) Urine drug testing should be utilized to assess for the presence of other medications and illicit substances;
- 11) Avoid concurrent benzodiazepine and opioid treatment; and
- 12) Arrange treatment for patients with opioid use disorders.¹⁵³

50. The CDC Guideline runs counter to prior consensus statements and clinical guidelines in several ways. For example, very early in the opioid epidemic, the American Academy of Pain Medicine and the American Pain Society issued a consensus statement that endorsed the use of opioids to treat chronic, non-cancer pain, arguing that "studies indicate that the de novo development of addiction when opioids are used for the relief of pain is low".¹⁵⁴ By contrast, the CDC Guideline underscores the risks of addiction and other adverse events related to prescription opioids, recommend lower dosages, focus on improving safe use among all, rather than "high-risk", patients, and provide more specific guidance regarding how to best

¹⁷ While the CDC Guideline is one of the most comprehensive, authoritative and widely cited opioid guidelines, any academic detailing program as part of an abatement remedy should be based on an assessment of the most current and suitable sources of information for such a program.

monitor opioid use and establish thresholds for stopping them in the setting of unfavourable risks/benefit balance.¹⁵⁵

51. Training on the management of patients who have been maintained on chronic opioids is also important, especially the subset of patients on high-dose opioids (e.g., greater than 90 morphine milligram equivalents per day). Since patients using opioids chronically are physically dependent on them,¹⁸ they must not have their opioids abruptly discontinued, nor should tapering be performed unilaterally. An increasing number of guidelines for tapering opioids among these individuals are available.^{156,157} These guidelines include information on when tapering should be considered among patients on long-term opioid treatment, which often occurs when adverse effects or the risk of adverse effects (e.g., sedation, drowsiness, constipation, nausea) outweigh potential benefits with respect to reductions in pain and improvements in physical, psychological and/or social functioning.¹⁵⁸ The guidelines also speak to the optimal management of individuals who, based on taper failure, may fulfil criteria for persistent opioid dependence and who may be best managed through long-term opioid treatment with treatments such as buprenorphine or methadone.
52. The National Resource Center for Academic Detailing (NaRCAD), a center aimed to support clinical outreach education programs, provides an extensive directory of established provider education programs, including a section for those dedicated to opioid safety.¹⁵⁹ For example, Alosa Health is a non-profit that has deep experience in this area, including state- and nationwide campaigns.¹⁶⁰ While pharmaceutical companies and pharmacy benefits managers both have extensive workforces available for direct prescriber outreach, neither would be credible in this setting given the conflicts of interest that would be posed. Instead, provider education programs typically recruit physicians, nurses, pharmacists or other individuals with a background in related health disciplines to conduct outreach.
53. Regardless of the detailer's background, it is essential that educators have no potential commercial conflicts of interest, have a background in a health discipline such as medicine or pharmacy, and receive rigorous training on how to conduct this outreach. Lack of clinical knowledge may cripple the detailer's credibility with the prescriber, making it difficult to establish a strong relationship that promotes rational prescribing. Furthermore, it is also important that the outreach is repeated over time, with follow-up visits to encourage positive changes and reinforce key messages.

¹⁸ Within a few weeks or less, all patients using opioids develop physical dependence, a predictable neurochemical change associated with sustained use. By contrast, addiction is far less predictable, represents compulsive use despite harm, and is often associated with impairment in social, psychological and/or physical functioning.

54. An academic detailing program should be included as part of any abatement plan within Cuyahoga and Summit Counties.¹⁹ Such an effort is feasible and could be highly scaled as well; numerous state-wide and even national provider education programs promoting safe prescribing have been conducted during the past two decades, including across Pennsylvania (e.g., Department of Aging Pharmaceutical Assistance Contract for the Elderly (PACE) Academic Detailing Program),¹⁶¹ Massachusetts (e.g., Boston Medical Center's Transforming Opioid Prescribing in Primary Care)¹⁶² and the United States Department of Veterans Affairs (e.g., National Academic Detailing Service).¹⁶³ Many health systems, including large integrated delivery networks such as the Kaiser Permanente,¹⁶⁴ have also executed such programs. Careful review of the evidence indicates that academic detailing works and would be an effective abatement tool.¹⁶⁵
55. In addition, while training and professional development of health care personnel such as doctors, nurses and EMTs is vital, additional educational capacity-building, as well as technical assistance, must be employed if the opioid epidemic is to be successfully addressed. For example, hospitals, health systems, integrated delivery networks, physician practices, long-term care facilities and other health care institutions and organizations should work diligently to incorporate educational programming and professional development services that assist in raising awareness and disseminating knowledge regarding the drivers of the opioid epidemic, as well as the role of their respective institutions in addressing it. Health systems play an especially important role given their broad reach and ability to promulgate evidence-based guidelines, as well as to engage in opioid stewardship.¹⁶⁶ Technical assistance to the courts, law enforcement, substance use treatment providers and other stakeholders should also be provided so as to ensure that these entities are kept abreast of the changing contours of the epidemic and the most relevant advances in prevention, treatment and recovery.

CATEGORY 1B. IMPROVING PAIN TREATMENT

The goal of this remedy recognizes the principle of improving the care of those with pain (see Paragraph #29). This is important because the under-treatment of pain served as one of several rationales for the large increases in opioid prescribing that occurred between 1996 and 2010, as many as two-thirds of adults with opioid misuse report pain as the reason for such misuse,¹⁶⁷ and many individuals with diagnosed opioid use disorder also report chronic pain.^{168,169}

56. Fortunately, there is increasing acknowledgement of the limited evidence supporting the use of opioids for the management of chronic pain.^{170,171} Combined with many studies nevertheless demonstrating their common use in this setting, this has underscored the importance of improving the management of individuals with acute and chronic pain, including through a focus on comprehensive assessments, multidisciplinary management and functioning rather than pain levels per se. Opioids represent just one of a large number of

¹⁹ Here and throughout, while I suggest remedies that should be included as part of a comprehensive abatement plan, I leave it to the communities themselves to determine whether elements of any given remedy are already in place and the degree to which further investment should be undertaken.

pharmacologic and non-pharmacologic treatments that providers and patients may use for the treatment of pain. Alternative pharmacologic treatments include acetaminophen, non-steroidal anti-inflammatories (NSAIDs), antidepressants, anticonvulsants, and topical analgesics,¹⁷² while non-pharmacologic treatments for pain include physical therapy, occupational therapy, chiropractic care, acupuncture and psychological interventions.¹⁷³ In addition, the care of pain among those already engaged in opioid misuse or with opioid use disorder requires additional skill and training given the need for clinical management of both.

57. As an abatement remedy, several complementary strategies should be used to improve the identification and management of individuals with acute and chronic pain in Cuyahoga and Summit Counties. First, it is critical to design, deploy and continually evaluate educational programs and outreach initiatives for health care providers. While there is an urgent need for a coordinated, evidence-based, national approach to pain education across federal agencies, such as the FDA, CDC and DEA¹⁷⁴, implementation of comprehensive pain curricula across Cuyahoga and Summit Counties through coordination among local and regional stakeholders (e.g., state professional societies, hospitals, health systems) should be pursued. Second, hospitals, health systems and ambulatory practice sites must invest in expanding their workforce and resources devoted to pain management (also see Paragraphs #41 and #99). While most patients with acute and chronic pain can be suitably managed by primary care or Emergency Medicine physicians, a subset of patients have complex, chronic pain syndromes and require greater levels of supervision and care coordination that is overseen by pain specialists. Third, remedies to improve the treatment of OUD should also include investments to improve the identification and management of chronic pain that is often present among these individuals.^{175,176} As I note in Paragraph #40, coverage and reimbursement policies are also an important determinant of care patterns for pain as well as opioid use disorder.¹⁷⁷

CATEGORY 1C. PRESCRIPTION DRUG MONITORING PROGRAMS & CLINICAL DECISION SUPPORT

The goal of this remedy is to improve the information available to support prescribers and law enforcement as they optimize the care of patients with pain as well as reduce opioid diversion. This is important because clinical information systems can enhance the quality of care that providers deliver, and prescription drug monitoring programs can be used by law enforcement to investigate aberrant patterns of controlled substance prescribing.

58. Prescription drug monitoring programs (PDMPs) are electronic databases that can be used to gather, curate and disseminate information about controlled substance prescribing within a state. By providing prescribers and pharmacists access to information regarding a patient's controlled substance history, PDMPs can be used to identify individuals with high risk prescription opioid use. PDMP data may also be useful to law enforcement and professional licensing boards to identify possible misconduct, and consequently implement administrative action, such as revoking state authorization to prescribe controlled substances. Despite this, it is important to emphasize, as discussed in Paragraph #33, that the opioid epidemic has not

been primarily driven by “bad doctors” or “bad patients”, and a misplaced focus on such a notion as PDMPs are deployed and implemented will limit their ultimately effectiveness at reducing opioid-related injuries and deaths.

59. Although there is conflicting literature on the impact of PDMPs, evidence suggests that PDMP implementation is associated with decreases in opioid prescribing, morbidity and mortality,^{178,179,180,181} especially in the setting of states’ legal requirements that health care providers query a PDMP in at least some circumstances.¹⁸² Currently, all 50 states, the District of Columbia, Guam and Puerto Rico have a PDMP that is operational or have indicated an intention to establish a PDMP.¹⁸³ While PDMPs are state-level programs, interstate sharing of PDMP data has also been undertaken and may be especially valuable in parts of the country where individuals are especially likely to seek care and receive prescriptions from providers and pharmacies located in different states;¹⁸⁴ in 2017, Ohio’s Automated Rx Reporting System (OARRS) expanded its functionality by allowing for linkage with Pennsylvania’s PDMP program, completing the ability of OARRS users to review controlled substance PDMP data from each of Ohio’s border states.¹⁸⁵
60. Despite the benefits of PDMPs and their ubiquitous adoption, historically many providers have failed to routinely register or use them except in states where such registration or use has been mandated. In a national survey of primary care physicians we performed in 2014, a majority of physicians were aware of their states’ PDMP and had a generally favourable belief regarding its value, yet these same providers reported that they did not access the PDMP consistently.¹⁸⁶ According to a 2015 report from the Journal of the American Medical Association (JAMA), the national median PDMP registration rate was 35% amongst licensed prescribers.¹⁸⁷ Since 2015, states have continued to evolve their programs and policies, with a strong trend towards states increasingly requiring mandatory PDMP registration and use.¹⁸⁸
61. PDMPs can be optimized by mandating that prescribers review PDMP data; allowing prescribers to delegate staff (e.g. nurses) to optimize workflow; requiring 24-hour or real-time reporting after dispensing a controlled substance; streamlining the registration process for PDMP participants; offering providers financial incentives based on PDMP use; and supporting educational and promotional initiatives such as workshops to train prescribers on how to access and use PDMP data.¹⁸⁹ Though it is still a growing practice and many barriers remain,^{190,191} integrating PDMP data with other electronic health information systems can provide clinicians with a more complete medical record collated in a single source to support clinical decision-making.¹⁹² Other interventions to optimize PDMPs address their use by law enforcement. While some of these applications require legislative or administrative intervention, they nevertheless represent potential innovations that could be supported through increased infrastructure and funding as part of an abatement remedy.
62. PDMP data, particularly, when integrated with other health information technology, such as electronic health records (EHRs), can also be used as the basis for clinical decision support

systems (CDSSs).²⁰ CDSSs may consist of automated alerts, reminders, templates, or care guidelines that are designed to provide providers, patients or other members of the care team with customized, just-in-time information to improve health care quality. In this instance, such systems can be used to help improve quality of care of individuals with chronic pain or opioid use disorder, such as by providing lower defaults for the number of opioids dispensed on a first fill, prompting screening criteria for OUD, or by alerting clinicians when they are seeing a patient on chronic opioids who has already experienced an overdose or other serious adverse event.²¹

63. Although relatively few studies have examined the effect of CDSS in the context of the opioid epidemic,^{193,194,195} there is a much larger literature that has examined the effects of CDSS in other contexts. As a whole, this literature underscores that while the use of electronic health records may not automatically translate into higher quality care,¹⁹⁶ many CDSSs improve provider performance,¹⁹⁷ and several features of such systems may drive improvements in clinical practice, including their incorporation into the workflow and provision of recommendations, rather than simply assessments, in a “just-in-time” fashion.¹⁹⁸
64. CDSS are facilitated by electronic prescriptions, which should be universally adopted as an additional technological approach to improve the safety and security of opioid and other controlled substance prescribing and dispensing. There are many advantages to electronic prescribing, which can reduce errors and fraud while improving the ability for surveillance as well as security through measures such as two-factor authentication.^{199,200}
65. Ohio’s PDMP, OARRS, began operation in 2006.²⁰¹ It is housed in Ohio’s Board of Pharmacy, an agency that has dual roles focused on both health as well as law enforcement, which may help facilitate PDMP implementation. The OARRS collects information every 24 hours on all outpatient prescriptions for controlled substances, as well as one non-controlled substance (gabapentin) dispensed by Ohio-licensed pharmacies and personally furnished by Ohio prescribers. Drug wholesalers are also required to report on a monthly basis information on all controlled substance and gabapentin that were sold to an Ohio licensed pharmacy or prescriber. The OARRS serves multiple functions, including minimizing the risk of drug-drug interactions, allowing for prescribers to review reports of their own prescribing,²⁰² assisting law enforcement in cases of controlled substance diversion and identifying clinicians with patterns of inappropriate prescribing/dispensing. Since November 2017, Ohio drug courts

²⁰ In other words, the value of PDMPs extends past identifying “opioid shoppers” or “rogue prescribers”; while these individuals are important to identify, they are a symptom of rather than the primary driver of the opioid epidemic (see Paragraph #33). Rather, PDMPs have the potential to improve pain management services, such as for individuals at risk of opioid misuse.

²¹ Shockingly, evidence suggests that more than nine out of ten patients who have a non-fatal overdose during long-term opioid use for non-cancer pain receive subsequent opioid prescriptions (Laroche MR, et al. *Ann Intern Med.* 2016;164:1-9).

have also been provided access to OARRS information, which may aid drug courts in ensuring that participants are complying with court ordered treatments.

66. As with many states, OARRS continues to transform as the state works to address the evolving epidemic. For example, prescribers are now required to review OARRS prior to initial prescription of opioids or benzodiazepines,^{22,203} and there are increasing efforts to integrate OARRS within health systems' electronic medical records so as to minimize disruption of work-flow.²³ There is also increasing interest in using PDMPs such as OARRS for clinical decision support. The ultimate utility of OARRS is only as good as the resources that are devoted to it, and thus, as part of any abatement remedy, resources should be committed to offsetting its future operational costs, expanding its functional integration within the electronic medical record systems of hospitals, health systems and other service providers in the State, and increasing its usability and value among law enforcement.

CATEGORY 1D. PATIENT AND PUBLIC EDUCATION

The goal of this remedy is to raise awareness and activate patients and the general public regarding the risks of opioids as well as the prevalence and treatability of opioid use disorder. Patient and public education can help to address the fact that many people do not understand the risks of opioids or the fact that opioid use disorder is a treatable brain disease. It can also chip away at stigma, which serves as a profound barrier to treatment.

67. Patient education is an important method of improving the safe use, storage and disposal of opioids, since there are important shortcomings in patients' knowledge regarding these matters. For example, the 2016 CDC Guideline highlights the importance of clinicians discussing with patients the known risks and realistic benefits of opioid therapy before initiating treatment.²⁰⁴ Other professional societies and organizations, such as the Veterans Administration/Department of Defence Clinical Practice Guideline for Opioid Therapy for Chronic Pain, also emphasize the importance of patient education as part of a multi-faceted strategy to maximize the risk/benefit value of opioids in clinical practice.²⁰⁵
68. In contrast to public education, which is addressed below, clinicians play an especially important role in educational outreach targeting patients who may be using opioids or otherwise at risk for opioid-related adverse events. However, clinicians themselves must be equipped to conduct such education, and their preparation for this can be maximized through academic detailing or other educational outreach. In addition, the CDC has prepared a number of educational materials for patients focused on promoting safer opioid use and minimizing the risk of overdose,²⁰⁶ SAMHSA's Opioid Overdose Prevention Toolkit includes a

²² Prescriptions for seven-day supplies or less are exempt from the mandate.

²³ To be clinically useful, PDMPs have to be accessible within the electronic health record system, rather than requiring a separate username and password. As one expert put it to me, "if it is more than two clicks away, it is worthless".

module providing safety advice for patients and family members,²⁰⁷ and other organizations, such as the American College of Surgeons,²⁰⁸ have developed their own messaging that can be used to educate patients regarding different aspects of the opioid epidemic.

69. Public education is also a crucial component in abating the epidemic, and one important way to conduct such education is through mass media campaigns. Properly designed and branded, such campaigns can deliver “sticky” messages, that is, messages that are concrete, memorable, contagious and therefore, impactful.²⁰⁹ Such messaging can serve as part of an effective intervention to positively change health behavior.²¹⁰ Despite this, not all mass media campaigns have been successful in achieving their desired impact²¹¹, and their success is dependent on several factors including the level and duration of investment made, the planning that goes into the campaign and the availability of concurrent treatment and other services. A mass media campaign may include a variety of media, including television, radio, billboards, and social media. Though there is limited literature on mass media campaigns focusing on opioids, there is robust information from campaigns on alcohol, tobacco and other illicit substances.
70. A number of these campaigns can be used as models when designing a nationwide campaign to address the opioid epidemic. For example, Idaho's Meth Project was aimed at reducing methamphetamine use through a comprehensive approach of public service announcements, community outreach, public policy approaches and in-school lessons. Following the campaign's initiation in 2007, Idaho experienced a 56% decline in meth use amongst teens.²¹² The U.S. Food and Drug Administration's award-winning youth tobacco prevention campaign, “The Real Costs”, is another example of a relatively recent mass media campaign. This campaign was launched nationally on multiple platforms, including TV, radio, print and social media. The campaign was focused on reaching youths, 12 to 17 years old in the United States, who were open to trying smoking or were already experimenting with smoking. In 2014-2016, high exposure to the campaign was associated with a 30% decrease in the risk of smoking initiation amongst youths.²¹³
71. While several mass media campaigns addressing the opioid epidemic have also been conducted,^{214,215} less is known regarding their impact, although early findings suggest their potential utility. For example, in January 2017, then New Jersey Governor Chris Christie rolled out the REACH NJ initiative aimed at raising awareness about the availability of new addiction treatment services in New Jersey.²¹⁶ The initiative included television ads airing on New Jersey, New York and Philadelphia television stations. As of January 2018, more than 18,600 people have called the ReachNJ hotline, with the frequency of calls at least three times higher in April-June 2017, when television and radio ads were on air, compared to July-August, when only digital ads were used.²¹⁷ Another example focused on opioids was launched by the Ohio Department of Health. This education and awareness campaign, Prescription for Prevention: Stop the Epidemic, has included public service announcements, drug disposal guidelines, and both county and state-level factsheets to prevent non-medical prescription drug use.²¹⁸ A third example was designed to raise awareness about a new law increasing naloxone access and providing legal protection for people who call 911 to report an overdose. This state-wide

media campaign, the Good Samaritan Law Awareness & Naloxone Access Media Campaign, was launched ~2013 by the North Carolina Harm Reduction Coalition (NCHRC), focusing on leveraging inexpensive platforms such as social media, printed flyers, public service announcements and local media. The NCHRC reported that the media campaign was effective in building connections with the local community and helping the organization become established as “the go-to expert for local media” regarding the opioid epidemic.²¹⁹

72. Any abatement program in Cuyahoga and Summit Counties should include investments in educational campaigns targeting patients and the general public. While both counties have invested in educational campaigns around drug disposal and safe opioid use over the past several years, including dissemination of SAMHSA materials, greater resources are required educate patients and the general public. Multimedia campaigns should include experts in health communications and public safety and be carefully designed to fully address widely prevalent yet insidious stigma that erodes effective community responses to the epidemic, treating addiction as a willful choice or moral failure and cleaving off addiction and its treatment from the rest of medical care.²²⁰ These campaigns must also educate the general public both about the risks of opioids as well as the prevalence and treatability of opioid use disorder. In addition, they should include messaging around the safe storage and disposal of opioids, since many individuals receiving opioids do not report having received such information.²²¹

CATEGORY 1E. DRUG DISPOSAL GUIDELINES AND PROGRAMS

This remedy respects the principle of intervening comprehensively all along the supply chain (Paragraph #28), including addressing enormous stockpiles of opioids in homes across America, by providing individuals with convenient opportunities to safely store and discard these unused medicines.

73. Safe storage and drug disposal guidelines are a critical component of public education, since the improper storage and disposal of unused prescription opioids is a widely recognized public health concern and an important component of the current opioid epidemic. In a 2017 systematic review that my colleagues and I published in JAMA Surgery, 67-92% of surgical patients reported having unused opioids after surgery, and in 2 studies examining storage safety, 73-77% of patients did not store their opioids in locked containers, resulting in a large reservoir of opioids which contributes to the misuse of these products.²²² Other studies also support the assertion that the safe storage and proper disposal of opioids is uncommon.²²³ The failure to safely store and dispose of unused opioids extends beyond surgical settings and contributes to the diversion of opioids as well as their non-medical use. For example, of the 11.4 million individuals in the United States reporting opioid misuse in 2017, more than four-fifths (83%) reported that they bought, were given, or stole opioids from individuals who were in turn prescribed these drugs by a licensed prescriber.²²⁴

74. Safe storage and drug disposal guidelines must be accompanied by increased availability of drug disposal programs, since these programs provide one avenue for proper disposal of

unused opioids.²²⁵ Some disposal programs are based on periodic events. For example, the U.S. Drug Enforcement Administration (DEA) hosts short-term events wherein temporary collection sites are set up for the safe disposal of unused prescription medicines. The DEA's most recent National Take Back Day was October 27, 2018, representing the participation of 4,770 law enforcement personnel and 5,839 collection sites that collected a total of 457.12 tons of prescription drugs.²²⁶

75. Other disposal programs are based on permanent collection sites authorized by the DEA, such as within pharmacies or law enforcement facilities (Figure 7). Unless disposal programs are convenient, they are unlikely to be widely used, and the use of pharmacies as part of a "reverse logistics" program, where the standard distribution system is reversed to return unused or unwanted product, has many efficiencies.²²⁷ Some authorized collection sites may also provide mail-back options to assist patients in disposing unused medicines, especially for homebound patients or others with special needs.



76. Historically, permanent collection sites have been uncommon due to administrative, legal and economic barriers. As of 2017, the United States Government Accountability Office reported that only 2,233 of 89,550 eligible entities (2.49%), such as pharmacies, hospitals/clinics, narcotic treatment programs, reverse distributors, distributors and manufacturers, were registered as authorized collectors of unused prescription drugs.²²⁸
77. There are four major components to consider when establishing a drug disposal program: promotion; staffing; equipment and supplies; and disposal.^{229,230} Programs can be promoted through varied means ranging from pharmacy posters or informational stickers on pill bottles to the use of social media to promote a drug disposal event. Staffing needs will vary based on the magnitude of work involved. Equipment, supplies and frequency of disposal will depend upon the volume of drugs collected. For example, a 6-month pilot program established in 5 different pharmacies in rural counties in New York collected an estimated 300 lbs. of prescription medicines in 2016.²³¹ By contrast, between 2014 and 2016 the Winchester Police Department's Drug Collection Unit collected approximately 1,240 lbs. of medication from a single, "24-7", collection site for unused and expired medications.²³²
78. Despite their importance, historically, drug disposal programs have only re-collected a small proportion of the total number of controlled substances dispensed, with collected drugs also including a mix of other medications such as antibiotics, oral contraceptives and cardiovascular treatments.²³³ Furthermore, the U.S. Food and Drug Administration directs that certain prescription medicines, such as opioids, should be immediately flushed down the toilet when no drug disposal program option is readily accessible.²³⁴ Patient and pharmacist education regarding how to properly dispose of opioids is important. In the absence of drug disposal programs, other routes of disposal include mixing unused opioids with inedible

garbage (e.g. cat litter) or using specialized chemicals that trap the unused pills in a non-divertible and biodegradable matrix.²³⁵

79. Any abatement program in Cuyahoga and Summit Counties should include investments to educate individuals regarding safe opioid storage, as well as to expand the availability and convenience of drug disposal programs. These programs should be implemented throughout community pharmacies as well as urgent care centers, hospitals, health systems, and law enforcement facilities. For select populations, such as homebound elderly or others with special needs, it may also be helpful to invest in mail-back options and/or distribution of biodegradable technologies that allow for safe and convenient at-home disposal.

CATEGORY 1F. EXPANDING SCIENTIFIC KNOWLEDGE

The goal of this remedy is to generate fundamental new knowledge that will ultimately translate into safer treatments for pain and opioid use disorder, as well as increased knowledge regarding how interventions can best be disseminated and implemented in communities across the country. The development of new treatments is important because both pain and OUD are common, and while both have a number of FDA-approved treatments, just as with treatments for cancer, cardiovascular disease and mental illness, these treatments are not perfect.

80. Scientific research is a key component in the fight to end the opioid crisis.²³⁶ Ensuring funding for scientific research will help to enhance the safety and effectiveness of current interventions as well as to develop new technologies and approaches to aid lawmakers, healthcare professionals, affected communities, and other stakeholders committed to addressing the crisis. In 2018, the National Institutes of Health (NIH) launched the HEAL (Helping to End Addiction Long-term) Initiative to speed scientific solutions to end the epidemic.²³⁷
81. Developing non-opioid and safer opioid pain medications is crucial to reduce reliance on addictive prescription opioids to address the problem of untreated pain. There are several, potentially promising, new treatments that remain under development. For example, animal studies of “biased opioid agonists” that produce pain relief via the mu-opioid receptor have produced promising yet very early results; the mechanism of action for these compounds does not depend on the “rewarding pathway” and does not cause respiratory depression like currently approved opioids.²³⁸ Other non-opioid-based approaches may also lead to new therapeutics such as brain-stimulation technologies, sodium channel blockers and cannabinoids. Accelerating research to further develop these approaches may offer patients with chronic pain and their healthcare providers more effective, and safer, less addictive, alternatives to currently available opioids.
82. Research is also needed to develop innovative technologies and medications to expand the number of treatment options for opioid addiction. Fortunately, there is ample evidence to support the effectiveness of current opioid addiction medications including the opioid agonist methadone, partial agonist buprenorphine, and antagonist naltrexone.²³⁹ However, not all patients are successfully treated with these MOUDs. Some experience cravings and

compulsions so powerful that they discontinue MOUD and return to active addiction. Others experience adverse effects from MOUD, such as nausea, abdominal pain or sedation, that prevent its continued use. Others are hindered by chaotic lives, social determinants of health (e.g., poverty, lack of education) and other factors (e.g. intimate partner violence, trauma) that disrupt adherence to a medicine regimen that generally requires daily administration and relatively high levels of functioning. Recent advances in the field include longer acting formulations of products such as buprenorphine that obviate the need for daily administration and decrease the potential for diversion; for example, a long-acting, once-monthly, clinician-administered, injectable formulation of buprenorphine was approved by the FDA in November 2017.²⁴⁰ Other advances that remain in earlier stages of development include vaccines that prevent opioids from entering the brain by utilizing the body's own immune system and safer treatments for opioid use disorders that depend on modifying brain circuits or that have novel molecular targets such as the kappa-opioid receptor.^{241,242}

83. While naloxone is an effective overdose-reversal intervention that has saved many lives,²⁴³ there is also an urgent need to develop additional overdose-reversal agents and technologies. In some cases, usual doses of naloxone are not sufficient to reverse fentanyl and other highly potent synthetic opioids overdoses.²⁴⁴ Additionally, bystanders may not reach persons who experience an overdose in time to administer naloxone. Developing new technologies and medications to reverse opioid overdose that are more powerful, longer-lasting, and that intervene automatically to stimulate respiration may decrease overdose mortality from opioids.
84. Although basic science and clinical research on safer treatments for pain and opioid use disorder are important, it is also vital to invest in scientific research that rigorously appraises community-level interventions to address the epidemic. For example, the National Institutes of Health's HEALing Communities Study represents an ambitious undertaking on the part of the NIH "to test the immediate impact of an integrated set of evidence-based interventions across healthcare, behavioral health, justice, and other community-based settings to prevent and treat opioid misuse and opioid use disorder within highly affected communities".²⁴⁵ While the precise nature of these programs has yet to be determined, interventions likely to be pursued include many of those discussed herein, ranging from prescriber education to naloxone distribution to expansion of OUD treatment within the criminal justice system. The primary motivation for this study is the fact that so many effective, evidence-based interventions to reduce opioid-related morbidity and mortality exist yet are not being adequately implemented and scaled in hard hit communities around the country. While the HEALing Communities Study is likely to make a valuable contribution to our knowledge of how to bring evidence-based interventions to scale, it is also important that resources are invested in carefully evaluating the effects of innumerable other interventions within clinical, behavioral health, justice, and other settings in communities across the U.S.
85. Local communities such as those within Cuyahoga and Summit Counties can play an important role in the generation of new scientific knowledge regarding how to best design, implement, and evaluate abatement remedies to reverse opioid-related injuries and deaths.

However, broad dissemination and implementation of successful strategies from Cuyahoga and Summit Counties will only be possible if the program evaluations are incorporated early and throughout the process of implementation of remedies.

CATEGORY 2: IDENTIFYING & TREATING INDIVIDUALS WITH OPIOID USE DISORDER (OUD)

The goal of this category is to better identify individuals with OUD and to remove clinical, economic and social barriers diminishing their access to comprehensive, coordinated high-quality care.²⁴ One important principle is to close treatment gaps. For example, some individuals who overdose in the field are not formally evaluated or successfully linked with treatment^{246,247}, while many others, even if brought to an Emergency Department, are discharged rather than transferred to an inpatient detox/rehabilitation facility, enrolled in an intensive outpatient (IOP) program or initiated on MOUD.²⁴⁸ However, many other interventions are necessary in addition to the closure of treatment gaps, including a transformation of the delivery system so that it “mainstreams” addiction care and delivers it as consistently and compassionately as it does care for pediatric cancer or amyotrophic lateral sclerosis (ALS).

CATEGORY 2A. TREATMENT FOR OPIOID USE DISORDER

The goal of this remedy is to provide patients with opioid use disorder readily accessible treatment. Such treatment should include access to FDA-approved MOUD, since these are efficacious treatments that not only reduce the likelihood of opioid use, but also the risk of overdose, criminal activity and the transmission of infectious disease.²⁴⁹ However, not everyone with OUD requires MOUD, and even when it is provided, it should be part of a full continuum of care, including care that addresses other acute, chronic and preventive needs.

86. People enter the treatment system multiple ways. Some have a near-fatal overdose and first have contact with EMTs or through evaluation in Emergency Departments or acute care facilities. Others come to the attention of Emergency Medicine, primary care, or other health care providers as they seek care for unrelated needs. Yet other individuals are first identified through syringe exchange programs or other harm reduction or community-based outreach, while some are identified through contact with the criminal justice system. There are opportunities to improve the identification and treatment of individuals with OUD within each of these settings, and the larger the gaps, the more people will fall through them. Therefore, multiple methods are needed to connect people to services, including through direct referral and transfer such as may occur from a hospital or Emergency Department, as well as through the use of a variety of human and technological resources including: 24-7 hotlines, or “treatment connectors”; web-based platforms to provide a centralized, easy to use repository

²⁴ It is also important to consider individuals with opioid dependence and non-medical use who may not yet fulfil formal criteria for an OUD; I consider these individuals in Paragraphs #170-174

of information for those seeking care; and adequate staffing of social workers, case managers and addiction counselors in clinical, behavioural, criminal justice and community settings.²⁵

87. The FDA has approved three medications for the treatment of OUD and the choice of medication should be tailored to the unique needs of each individual.

- 1) Methadone is an opioid agonist, which means it can activate opioid receptors in the brain and provide pain relief similar to other opioids. It can prevent withdrawal symptoms, reduce cravings and block the euphoric effects of other opioids. However, due to federal regulations, its dispensing for OUD is limited to certified opioid treatment programs, serving as a barrier to broader use.²⁵⁰
- 2) Naltrexone is an opioid antagonist that blocks the effects of other narcotics. Provided as a daily pill or monthly intramuscular injection, it can be prescribed in ambulatory settings and does not have any abuse or diversion potential.²⁵¹ However, it cannot be administered to individuals with opioids in their systems, since doing so will precipitate abrupt opioid withdrawal.²⁵²
- 3) Buprenorphine is a partial agonist and partial antagonist of the opioid receptor, with significantly lower potential to produce euphoria or respiratory depression than other opioids. Appropriately waived physicians may prescribe buprenorphine offices, community hospitals or correctional facilities.²⁵³ While the main form of buprenorphine for OUD is an orally administered combination of buprenorphine and naloxone (the latter of which is an opioid reversal agent as described in Paragraph #107), other formulations of buprenorphine are likely to be FDA approved in the years to come.²⁵⁴

88. Historically, some have opposed MOUD based on a number of misconceptions, including that it is invariably diverted (it is not, and when it is, it is often to avoid the dysphoria of opioid withdrawal including symptoms such as agitation, anxiety, muscle aches, nausea and vomiting),²⁶ or that it is simply substituting one addiction for another (it is not).²⁵⁵ Rather, MOUD increases social functioning and retention in treatment, allowing individuals a better opportunity to reintegrate within their families and communities and to transition from active addiction through treatment into recovery.^{256,257} It is also associated with a wealth of other positive outcomes, including decreased opioid use and improved survival.²⁵⁸ Because of this, its use is supported by numerous authoritative sources, including the Centers for Disease Control and Prevention, National Institutes of Drug Abuse, American Society of Addiction Medicine and Substance Abuse and Mental Health Services Administration. It is also supported by global authorities such as the World Health Organization, which includes

²⁵ These include, but are not limited to, Emergency Departments, hospitals and other acute care facilities, schools, the courts, jails, prisons, detention facilities, and syringe exchange programs and other community-based outreach programs.

²⁶ Even the need for such defense of MOUD underscores the marked stigma and asymmetry that exists between OUD and other diseases; for example, it is hard to imagine a setting where the use of inhalers for asthma, insulin for diabetes, or even psychotropics for mental illness, would be met with such skepticism or outright opposition.

buprenorphine and methadone as Essential Medicines.²⁵⁹ However, as I discuss further in Paragraphs #94 and #95, MOUD is not a stand-alone therapy nor does everyone require it; when it is used, it must be accompanied by other clinical interventions as part of comprehensive care for those with OUD.

89. Despite the potential of MOUD to help address the opioid epidemic, it is severely underutilized. For example, an analysis of 2012-2013 data from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) indicated that fewer than one in five individuals with non-medical prescription opioid use disorder were ever treated,²⁶⁰ and rates of use of MOUD within publicly funded treatment programs have historically been low.^{261,262} Combined with low use of MOUD even within programs offering it, some estimates are that as few as 1 in 10 individuals with OUD receive MOUD.²⁶³ Worsening matters further, treatment courses are often short, rates of treatment discontinuation and relapse high,²⁶⁴ and even periods of MOUD use are often punctuated by the receipt of prescriptions for non-MOUD opioids, underscoring common and serious lapses in care even for those accessing these treatments.^{265,266}

90. A 2018 study from Massachusetts provides useful context.²⁶⁷ In this analysis of adults who survived an overdose between 2012 and 2014, in the 12 months after an overdose, 11% received methadone, 17% received buprenorphine and 6% received naltrexone. The average (median) duration of treatment was short, 1-5 months. Both methadone and buprenorphine utilization were associated with decreased opioid-related and all-cause mortality.²⁷ Thus, this study underscores: (a) large gaps in MOUD adoption; (b) high discontinuation rates; and (c) the life-saving benefit of methadone and buprenorphine.

91. There are many barriers that account for the large gap between the number of individuals with opioid use disorder and the proportion that are treated with MOUD. Underlying these barriers are misconceptions about the nature of OUD and the effectiveness of MOUD, as well as other concerns such as those identified in Paragraph #88. In a recently published study based on national surveys, my colleagues at the Johns Hopkins Bloomberg School of Public Health found that only about one in three substance use treatment facilities offered MOUD in 2016, and fewer than one in sixteen (6.1%) offered all three.²⁶⁸ There is also a large shortage in the number of providers who are equipped to provide care for those with addiction.^{269,270} Finally, the costs of MOUD, as well as other treatments for opioid disorder, have historically been an impediment for many individuals who might otherwise seek care.²⁷¹ While our own work^{272,273}, and that of others²⁷⁴, suggests that health plans are increasingly modifying their coverage and reimbursement policies so as to address the opioid epidemic, many individuals with opioid use disorder still face economic barriers to treatment, with a 2016 Department of

²⁷ The authors speculated several reasons they may not have observed a statistically significant benefit with naltrexone, including a small sample and short duration of use, with most patients receiving it for a single month. In addition, the study was unable to differentiate oral from intramuscular naltrexone.

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Defense estimate of the costs of MOUD^{28,275} exceeding that of diabetes mellitus (\$3,560) or kidney disease (\$5,624).²⁷⁶

92. Overcoming these economic and structural barriers is just the first step in achieving the potential for high quality OUD care.²⁷⁷ This is because there is enormous stigma associated with opioid addiction, which discourages patients from seeking treatment and discourages clinicians from providing it.²⁷⁸ While opioid use disorder is a brain disease, it is often framed as a moral failing instead; treatment systems remain marginalized rather than “mainstreamed”; language about “legitimate pain” and “junkies” and “getting clean” perpetuates such marginalization; and many features of the criminal justice system’s intersection with opioid use disorder also contribute to the persistent organizational failures that are seen.²⁷⁹
93. Improving treatment uptake and use for OUD is not just the right clinical thing to do, it also makes good economic sense. For example, Ettner and colleagues²⁸⁰ and Gerstein and colleagues²⁸¹, have estimated at least a 7:1 return on investment when examining the economic benefits and costs of the treatment of alcohol and drug disorders using California treatment data. These and other data are helpful in suggesting the value of MOUD, although there is also a need for further research that is focused specifically on treatments for OUD, rather than broader substance use disorders such as alcohol use disorder or use disorders associated with other controlled or illicit substances.
94. Investments in the treatment infrastructure must be made along a full continuum of care, from overdose reversal and acute detox to supports enabling long-term recovery. Individuals with OUD need regular contact with health care professionals responsible for supervising their pharmacologic and/or behavioral treatments, screening for adverse events or treatment failures and delivering supportive care and psychological counselling. In many ways, such a model is no different than a model of care for someone with asthma or diabetes. These diseases, and their treatments, can’t be managed in a vacuum. Medications, whether MOUD or treatments for other chronic diseases, should be provided in the context of a therapeutic relationship where risk factor attenuation, supportive counseling, medication monitoring, and attention to other health care needs take place. In the case of OUD, the delivery of structured social support and counseling may be especially important, given that these engagements assist patients in establishing the social reconnection that can be critical to long-term recovery. Treatment must also recognize the importance of screening and treatment for infectious diseases such as Hepatitis C and HIV²⁸², as well as attending to chronic pain, other substance use disorders and mental illness, all of which are common among individuals with non-medical opioid use or OUD.²⁸³
95. In addition, no single treatment is right for everyone, and not every individual with a history of opioid use disorder should be treated with MOUD. For example, some people have a

²⁸ Estimated annual costs, which included a number of assumptions and were framed as preliminary, were \$6,552 (methadone), \$14,000 (naltrexone) and \$5,980 (buprenorphine).

remote history of opioid use disorder and while they retain a lifelong sensitivity and vulnerability to opioids, just as an alcoholic does to alcohol, many of these individuals are living productive, successful lives in recovery without MOUD. Some individuals are able to maintain healthy recovery through abstinence-based, 12-step programs such as Narcotics Anonymous, psychological counselling and supportive therapy, or combinations of these or other approaches.

96. There are many different models for expanding access to OUD treatment within communities such as Cuyahoga and Summit Counties, and this remains an area of rapid growth and program evaluation. For example, Office-Based Opioid Treatment (OBOT) allows for physicians completing a waiver program to prescribe buprenorphine for OUD within primary care settings, the Medicaid Health Home Model integrates MOUD and behavioral health treatments with primary care for people with OUD and the Hub-and-Spoke Model triages patients between primary care clinics for uncomplicated patients with OUD (the “spokes”) and centralized clinics equipped to care for patients requiring methadone or whose complex behavioral and medical needs exceed those routinely provided in primary care settings.²⁸⁴ Other models employ telemedicine or evaluate the increasingly common induction of MOUD within Emergency Department or inpatient settings.²⁸⁵
97. These programs differ along many dimensions, such as the degree to which they focus on the delivery of pharmacotherapy, behavioral services, care integration and community-based education or outreach. It is important that programs are designed to deliver care to individuals who have initiated MOUD, or “induction”, in low-barrier settings such as syringe exchange programs or emergency departments, given that the marginalization and social isolation of some of these individuals increase their likelihood for relapse or loss to follow-up. As discussed elsewhere, the needs of communities differ, and the optimal program for a given city or county will depend upon a variety of different factors including the adequacy of the primary care and specialty workforce, urbanicity, and existing infrastructure devoted to addiction treatment.
98. Most individuals with opioid use disorder who are entering treatment can be managed either in an ambulatory or intensive outpatient (IOP) setting, although initial evaluation and appropriate triage is important so as to optimize each individuals’ likelihood of successful treatment and recovery. IOP programs typically provide for several hours of patient engagement four to five days per week for a period of several weeks, and may include services ranging from individual, group and/or family counseling to case management to vocational training and employment services.²⁸⁶ A minority of individuals with opioid use disorder require inpatient hospitalization for initiation of detoxification and treatment, such as when acute illness (e.g., pneumonia or soft tissue infection), advanced comorbid disease (e.g., heart failure or liver failure) or uncontrolled psychiatric illness (e.g., bipolar affective disorder) makes ambulatory or IOP treatment unfeasible.
99. Workforce expansion is also important as part of efforts to build treatment infrastructure, given that many communities lack a sufficient number of well-trained health care professionals

who are equipped to deliver needed services for those living with chronic pain and/or opioid use disorder. These shortages have been experienced in Ohio;²⁸⁷ for example, in a survey of specialty addiction treatment organizations in the state, nearly half of the surveyed facilities reported insufficient prescribing capacity and one in four facilities using buprenorphine reported they had to turn patients away.²⁸⁸ There are a number of complementary mechanisms to prepare the workforce, including greater training through existing graduate health professional education programs as outlined in Paragraph #41 and elsewhere in this report, as well as capacity-building through expansion of existing infrastructure and the creation of new programs for health care professionals and paraprofessionals.²⁸⁹

100. Any abatement program within Cuyahoga and Summit Counties should include investments in the treatment system so as to allow for the provision of comprehensive, coordinated high-quality care for individuals with OUD, including access to services for the identification and management of acute, chronic and preventive care needs.²⁹⁰ Cuyahoga and Summit Counties already have taken significant steps to expand treatment capacity.²⁹¹ Even so, only a small percentage of residents who could benefit from treatment are receiving it, and more must be done to connect individuals to appropriate services. Such investments should be also targeted at each specific points where gaps occur or individuals otherwise experience unacceptably high rates of relapse or loss to follow-up, ranging from the identification and triage of patients after non-fatal overdose to the expansion of detox and IOP programs to the provision of compassionate, evidence-based care for individuals living in recovery.

CATEGORY 2B. PEER COACHES, RECOVERY HOUSING AND JOBS TRAINING

The goal of this remedy is to increase the use of peers, who have credible, lived experience with opioid addiction, as well as to provide recovery housing and employment or vocational training for individuals whose recovery from opioid addiction might otherwise be jeopardized by the absence of a stable, supportive home environment or opportunities for gainful employment and career advancement.

101. While there is an urgent need to train more primary care practitioners to identify and treat opioid use disorder, peer recovery coaches also can play an important role in the treatment and recovery process for some individuals with OUD. The primary value of a trained peer coach is their lived experience with addiction, which allows for them to provide a level of credibility and authenticity that can be enormously helpful for individuals entering the treatment system. Coaches may provide a number of different types of resources or support to individuals with OUD, ranging from psychological support to connections to recovery communities, activities and events.²⁹² Two systematic reviews examining the impact of peer-recovery services suggest the positive impact that such services can have on those with substance use disorders.^{293,294}
102. Recovery housing is also an important component of care for some people with OUD. The National Alliance for Recovery Residences (NARR) defines four levels of recovery housing ranging from self-funded, peer-run, residential facilities where individuals can stay indefinitely

(Level 1) to residential facilities that also serve as clinical treatment centers (Level 4).²⁹⁵ As explained by Lori Criss, the Associate Director of the Ohio Council of Behavioral Health & Family Services Providers, "Who we spend our time with, where we go, and the things we surround ourselves with all impact who we are and the decisions that we make. Many times, people in early recovery have to give up everything they've known... because those people, places, and things put them at risk for relapse or continued use. Early recovery can be painful and isolating. Recovery housing can fill that void with a safe place, compassionate people, and a life full of purpose and fun that doesn't involve alcohol or drugs."²⁹⁶

103. As with peer recovery coaches, evidence examining the effect of recovery housing on outcomes such as drug and alcohol use, employment and psychiatric symptoms, while limited, suggests salutary effects.²⁹⁷ However, concerns have also been raised regarding substandard or outright fraudulent services being provided by some recovery houses. A March 2018 report from the U.S. Government Accountability Office (GAO) examining this matter in five states, including Ohio, underscores both the potential promise of recovery housing as well as the importance of adequate state regulatory oversight of their practices to ensure the prevention of exploitative or outright fraudulent housing practices.²⁹⁸
104. The role of the workplace in impacting the opioid epidemic must also be considered. For example, individuals with OUD who are under- or unemployed need opportunities for vocational training and access to employment, since unemployment is a significant risk factor for substance use, as well as relapse.²⁹⁹ In addition, prevention programs should be developed to broader populations of under- and unemployed through job training programs and other mechanisms, so as to decrease the likelihood of new cases of non-medical opioid use or OUD among this population.
105. The workplace is also important to consider because of the myriad ways that employers can positively impact the opioid epidemic.³⁰⁰ For example, employers should develop programs and policies that support employees living with chronic pain or who seek or are in treatment or recovery from opioid use disorder, including ensuring sufficient coverage and reimbursement of comprehensive services along the full continuum of care for OUD.³⁰¹ Employers can also create a workplace that is supportive of treatment and recovery by ensuring that hiring policies do not discriminate against individuals with a history of substance use disorder or criminal records secondary to such disorders.
106. Abatement remedies in Cuyahoga and Summit Counties should include resources to support a cadre of peer recovery coaches available to work directly with individuals entering the treatment system. In addition, investments should be made to maximize the availability and quality of recovery housing for individuals with OUD who are in need of such services as part of their recovery. Cuyahoga and Summit Counties have expanded recovery housing in recent years, but capacity is still not sufficient to serve everyone who could benefit from such services or for sufficient duration.^{302, 303} Finally, individuals with OUD who are under- or unemployed should be provided opportunities for career advancement through employment or vocational training programs that equip them to enter the workforce so as to maximize their likelihood

of a healthy and successful recovery, and employers should develop policies that affirm the workplace and societal value of individuals who have been harmed by the epidemic.

CATEGORY 2C. NALOXONE DISTRIBUTION AND TRAINING

This abatement category focuses on naloxone distribution and training. Naloxone is an opioid antagonist, or "blocker", that can save lives by safely and rapidly reversing opioid overdoses. However, its costs, stigma and other barriers have historically limited accessibility to those in need.

107. As an opioid antagonist, naloxone works by binding to opioid receptors and blocking respiratory depression and other effects of prescription opioids and heroin or illicit fentanyl. It only works if someone has opioids in their system. Naloxone is a non-scheduled prescription medicine rather than a controlled substance.
108. There is widespread consensus that naloxone distribution and training represent an important method to reduce opioid-related overdose³⁰⁴, and reductions in opioid overdoses, including in areas such as Dayton, Ohio, have been attributed in part to widespread campaigns to improve the availability and use of naloxone.³⁰⁵
109. Naloxone can be easily administered through three FDA-approved formulations: injectable, autoinjector delivered and nasal spray, and it has little risk of adverse events. Injectable naloxone requires professional training, but it is also the least expensive since naloxone is no longer under patent protection.³⁰⁶ The autoinjector, branded as Evzio®, was approved in 2014 and is most expensive. It has also been suggested to offer the easiest usability.³⁰⁷ The nasal spray, branded as Narcan®, was approved in 2015 and is favored by some given its usability and price. As with MOUD, additional formulations and continued innovation in the naloxone market are highly likely, and abatement remedies should remain flexible to keep pace with these changes.²⁹
110. The price of naloxone is important to consider because historically its costs have been an important barrier preventing more widespread availability and use. For example, a two-dose package of the auto-injector Evzio was priced at \$690 in 2014 but \$4,500 in 2016, representing more than a six-fold increase in price over the course of two years.³⁰⁸ In response to surging demand for naloxone, as well as its escalating costs, some cities and counties have had to ration it.³⁰⁹
111. While the costs of naloxone have prevented its more widespread availability and use, other barriers are also important to consider. These include stigma surrounding opioid use disorder, which impacts the readiness and willingness of individuals to engage with its preparation or use, as well as training requirements regarding its use.^{310,311}

²⁹ For example, it is plausible that a new formulation of naloxone may be developed and brought to market that has a significant comparative advantage over currently available naloxone formulations.

112. Three different channels should be used to increase naloxone distribution and use. First, health care providers and first responders, such as law enforcement and EMTs, should be provided with naloxone and training, since these individuals often serve as the initial point of contact with those who have overdosed. Second, high risk patients, such as those who are maintained on chronic, high-dose prescription opioids or who have already experienced a non-fatal overdose, should be prescribed naloxone and trained on how to administer it. In many cases, such training should also include their caregivers and/or family members, given the likelihood that these individuals would be most likely to be the ones responding to an overdose. Finally, naloxone should be distributed throughout communities in public spaces, similar to automatic external defibrillators which are routinely available in movie theaters, malls, schools, airports and houses of worship.
113. Despite its benefits, naloxone distribution and training will have a finite impact on the opioid epidemic. Not all overdoses are witnessed by someone willing and able to administer naloxone. In addition, the long-term public health impact of naloxone programs depends on what happens after an overdose is successfully reversed. For example, successfully revived individuals remain vulnerable to future overdose and death, and individuals who overdose once have escalating risks of future overdoses.³¹² After naloxone, individuals may temporarily or permanently desist from use, continue as active users, obtain addiction treatment, overdose again, or die of other causes. Ultimately, the outcomes of an overdose reversal depend upon the availability and comprehensiveness of OUD treatment, other mortality risks and background factors. These factors underscore the importance of a comprehensive abatement approach.
114. There have been several efforts to improve the utilization and access to naloxone in Ohio. Initiated in 2012 by the Ohio Department of Health, Project DAWN (Deaths Avoided With Naloxone) is a community-based overdose education and naloxone distribution program created to combat Ohio's opioid overdose crisis.³¹³ Participants of Project DAWN receive training on how to recognize signs and symptoms of overdose, as well as learn overdose response protocols, such as rescue breathing, calling emergency services and administering intranasal Naloxone. Several Project DAWN and naloxone access sites exist across Ohio, including sites in Cuyahoga County and Summit County. In Cuyahoga County, Project DAWN was attributed with saving ~900 lives in 2017 and was projected to save another ~700 lives in 2018.³¹⁴ In Summit County, two new sites were opened in 2018 as part of Project DAWN. One site reported 167 opioid overdose reversals due to Project DAWN within the first six months of operation.³¹⁵ Despite this, as Katherine Keyes outlines in her report, more resources are needed to adequately scale up naloxone across Cuyahoga and Summit Counties.
115. Cuyahoga County has also implemented a collaborative naloxone initiative between Discount Drug Mart, wherein the Cuyahoga County Board of Health and the MetroHealth System aimed at creating a protocol to begin distribution of naloxone at every Discount Drug Mart throughout Ohio.³¹⁶ As of 2016, all Discount Drug Marts in Ohio were equipped to dispense naloxone kits to individuals without a prescription³¹⁷. This initiative has included educating pharmacists and pharmacy technicians on addiction paradigms and how to provide naloxone,

as well as the creation of a pain medication awareness pamphlet distributed with every opioid filled at Discount Drug Marts in Ohio.³¹⁸

116. Any abatement program within Cuyahoga and Summit Counties should ensure that naloxone is readily available to all in need, including first responders and high risk patients, as well as distributed effectively in public spaces. Naloxone distribution should be accompanied by direct training, and its role in reversing overdoses should also be considered for inclusion in educational campaigns as discussed elsewhere herein.

CATEGORY 2D. HARM REDUCTION INTERVENTIONS

The goal of harm reduction is to implement evidence-based interventions that “meet people where they are at”. Such approaches recognize the formidable barriers that often prevent people from treatment seeking or achieving full recovery; harm reduction diminishes individual and societal harms from the opioid epidemic.

117. Harm reduction refers both to a set of general principles used to underpin policies concerning the way that societies respond to drug problems and to specific interventions. A defining feature of harm reduction is its focus on harms associated with opioid use rather than the prevention of such use per se. Harm reduction approaches can target individuals as well as the structural (e.g., drug paraphernalia laws)³¹⁹ and environmental (e.g., physical environment) contexts which engender harm.
118. Harm reduction can be contrasted with approaches that prioritize the singular prevention of drug use, which often are embodied in “zero tolerance” enforcement approaches.³²⁰ Empirical evidence has demonstrated short-comings of the U.S. “War on Drugs,”^{321,322} including its failure to reduce the demand for drugs^{323,324} or decrease drug-associated violence³²⁵ while leading to the disproportionate incarceration of people of color and the urban poor. Such findings underscore the need for innovative, evidence-based approaches to address opioid use disorder and other harms stemming from non-medical opioid use. An important component of any comprehensive response to the opioid epidemic includes scaled-up harm reduction services targeting people who are actively using drugs. There are three main harm reduction approaches that are relevant to the opioid epidemic.
119. Syringe Service Programs (SSPs). These programs are designed to provide clean syringe access and disposal to people who use drugs (PWUD) intravenously. Such programs were scaled up in the U.S., Europe and Australia in the 1990s and 2000s to help reduce the transmission of blood-borne infectious diseases. This is important because an estimated 4.1 million people in the U.S. are infected with HCV³²⁶ and ~1.1 million are infected with HIV, with about 25% of HIV cases co-infected with HCV.^{327, 328} While studies suggest only a small proportion of individuals with non-medical opioid use progress to heroin,³²⁹ there are nevertheless millions of individuals who report such non-medical opioid use, intravenous drug use (IVDU) is a primary risk factor for the acquisition and transmission of both HCV and HIV, and the opioid epidemic has resulted in a sharp increase in both of these diseases. From

2012 to 2016, the Centers for Disease Control and Prevention (CDC) estimated acute HCV infections have increased by ~70%,³³⁰ and states with the highest rate of new HCV infections, such as West Virginia, Kentucky, and Tennessee, are also among those that have been hardest hit by the opioid epidemic.³³¹

120. Beyond national statistics, a microcosm illustrating the interconnectedness of the opioid epidemic and HIV and HCV infections was seen in rural Scotts County, Indiana. In 2015, this rural county experienced a community outbreak of HIV, and by April 2016, there were 188 confirmed cases of HIV infection, of which 92% were coinfecting with HCV.³³² The Indiana State Department of Health led an investigation into this outbreak and determined it to be linked to injection drug use of the prescription opioid oxycodone.³³³ This outbreak also highlighted the vulnerabilities of communities to handle these crises.
121. The U.S. Public Health Service has long recommended to have a clean syringe for every injection, effectively increasing the “coverage” of sterile needles and syringes.³³⁴ Through extensive research over three decades, SSPs have been associated with reductions in risky syringe sharing behaviors^{335,336}, as well as rates of HIV^{337,338,339,340}, Hepatitis B and Hepatitis C.³⁴¹ SSPs also generally include onsite evaluation and referrals for substance use disorder treatment for an otherwise difficult to access population. As of October 2017, there were an estimated 310 syringe services programs in 42 U.S. states and Washington, D.C.³⁴²
122. SSPs often provide medical services for PWUD, many of whom are marginalized and may have otherwise very limited access to ambulatory care. In addition to doctors, nurses, and social workers, such care may include peer recovery coaches, whose potential value and services are discussed in Paragraph #101. Clinical services delivered as part of SSPs may include care for acute conditions such as upper respiratory infections, chronic conditions such as diabetes or cardiovascular diseases, or most commonly, preventive screening and other preventive interventions such as flu shots or other vaccinations. Such programs may also include family planning services. Individuals who test positive for HIV, HCV or both should be referred for treatment. Positively identified individuals will require access to necessary health care including effective antiretrovirals and direct-acting antiviral treatments that treat HIV and HCV, respectively, as well as treatment for their underlying OUD, including access to MOUD and other treatments for opioid use disorder.
123. Overdose prevention sites. Overdose prevention sites, or supervised consumption sites are places where people can legally use previously purchased prescription or non-prescription opioids (e.g., heroin, fentanyl) under medical supervision. These sites have been established in Canada, Europe and Australia for over 30 years and have been shown to decrease overdose death, transmission of infections and public drug use.^{343,344,345,346} Primarily staffed by medical or case management staff and current or former PWUD who do not assist in drug administration³⁴⁷, they are equipped to address questions about how to decrease the risks of drug consumption, provide sterile equipment (e.g., syringes) and condoms, and reverse overdose. In addition to their public health impact and cost-effectiveness, these sites are

uniquely effective in sustaining contact with the most marginalized PWUD who consume drugs in public places^{348,349}, and positively impact communities by reducing public drug use.³⁵⁰

124. Drug checking. Drug checking services enable people who use drugs to have the content of their drugs chemically analyzed, allowing them to make informed decisions about use.^{351,352} Drug checking, a method pioneered in Europe, has the potential to introduce the concept of product safety into the unregulated illicit drug supply in the U.S. Currently, its use in the U.S. has been limited to raves or similar parties, primarily for the testing of 3,4-methylenedioxy-methamphetamine (MDMA, or “ecstasy”). Recently, some syringe services programs in the U.S. have begun distributing fentanyl testing strips originally designed for testing urine samples. Such “fentanyl checking” allows users to objectively determine whether their drug samples contain fentanyl or fentanyl analogues. While few evaluations of fentanyl testing services have been performed, recent assessments suggested a high degree of acceptability and potential utility among PWUD.^{353,354,355}
125. Any abatement program in Cuyahoga and Summit Counties should include resources to support harm reduction services. Syringe exchange services, including outreach, delivery of non-OD care and referral for treatment, should be expanded sufficiently so as to reach the broadest population of individuals with IVU possible within Cuyahoga and Summit Counties. Such programs should include increased availability of drug checking services to assist in the rapid identification of fentanyl so as to allow users to avoid using heroin adulterated with fentanyl, which is far more lethal. For example, in 2018 Summit County Public Health began distributing fentanyl test strips in limited quantities, and has documented harm reduction for PWUD.³⁵⁶ While significant legal and policy reform will be required³⁵⁷, consideration should also be given to the establishment, and continual evaluation, of one or more overdose prevention sites, given evidence of a salutary public health impact.^{358,359,360}

CATEGORY 2E. SURVEILLANCE AND LEADERSHIP

The goal of surveillance is to convert local data to actionable intelligence at a local level by gathering, curating and disseminating timely information about key dimensions of the epidemic to public health officials, policy-makers and other stakeholders. This is important because the absence of timely, granular information about the epidemiology of opioid use, addiction and overdose at a local level has limited the ability of stakeholders to rapidly design, iterate and evaluate targeted interventions to address the epidemic in communities such as Cuyahoga and Summit Counties.

126. The opioid epidemic is a complex phenomenon with many different dimensions and impacts, and it continues to change and evolve rapidly at national, state and local levels. At a national level, prescription opioid sales increased approximately four-fold between 1999 and 2010³⁶¹, though since then, sales have modestly declined. Despite a plateauing of prescription opioid deaths, since 2010 there have been large increases in the rates of use and overdose deaths from heroin and illicit fentanyl.^{362,363} Other national changes, and some glimmers of hope, are

apparent, such as large declines in new users of heroin in 2017, as well as significant increases in ambulatory treatment among those with substance use disorders.^{364,365} However, enormous gaps remain.

127. At a local level, these changes have often been even more profound, as the opioid epidemic has impacted communities differently. For example, there is enormous variation in the volume of opioid prescribing, overall, and per capita, across different geographic regions of the United States³⁶⁶. Similarly, rates of illicit fentanyl, as well as overdose^{367,368}, vary widely, with some states, such as Ohio, Pennsylvania and Kentucky, having experienced disproportionately high numbers of overdoses compared with other states, such as Nebraska or Wyoming or Texas. Communities within these states have also been affected differently, both with respect to prescription sales or overdose deaths, as well as with respect to other important features of the epidemic, ranging from treatment capacity³⁶⁹ to spending on the epidemic.³⁷⁰
128. Policy-makers and public health leaders need timely and accurate information on key parameters they can use to make informed decisions about resource allocation. The importance of data is affirmed by the U.S. Department of Health and Human Service's Five-Point Opioid Strategy, which includes "Better Data" as one of the five key strategies to address the crisis.³⁷¹ Without such information, local communities are "flying blind", no better off than an airplane pilot without access to the plane's instrument panel. For example, the deployment, targeting and evaluation of academic detailing programs depends vitally on timely information regarding opioid prescribing across prescribers. Similarly, naloxone distribution and training should be designed based on the relative incidence, causes and outcomes of overdose within small, well-defined geographic areas.
129. Expanding surveillance capabilities is important at every level.³⁷² At a national level, the federal government must continue to invest in surveillance of opioid prescribing, addiction and overdose.³⁰ This information aids in quantifying populations at-risk and also provides insight regarding the effectiveness and unmet needs of prevention, treatment and recovery programs. The National Survey of Drug Use and Health has consistently provided valuable, annually updated data regarding some key features of the epidemic, but it is limited by several factors, including, under-coverage of high-risks groups such as homeless or institutionalized individuals as well as a focus on past-year rather than life-time or incident OUD.³⁷³ Similarly, the CDC Wonder online database provides the best single source of information about one vital measure of the epidemic - opioid mortality - yet causes of death are variably reported across states, and further work is needed to improve the uniformity and quality of data from medical examiners and coroners that is reported into this system.^{374, 375}

³⁰ Despite the value of national sources of information, there are often lengthy lags in availability and other features limiting its utility for cities and counties in need. Rather, cities and counties often have information that could be of great value, yet historically these communities have lacked the resources required to put these data to use.

130. At a state level, funding is needed to assist states who continue to expand and harmonize their reporting systems. Such efforts are already underway and have been partially underwritten by the CDC, which in 2016 and 2017 provided funding for 32 states and Washington D.C. to implement state-based opioid surveillance systems, designed to provide more timely and comprehensive data on fatal and nonfatal opioid overdoses and risk factors associated with fatal overdose.³⁷⁶ States need additional investments to build systems to increase the speed and comprehensiveness of overdose reporting, which should incorporate emergency medical services data as well as comprehensive toxicology testing by medical examiners and coroners. Such efforts should also include syndromic surveillance, designed to detect illness or disease prior to diagnostic confirmation. While such systems were first developed in response to bioterrorism threats, their structure and approach may be useful for some elements of surveillance of the opioid epidemic.
131. At local levels, cities and counties should invest in near real-time surveillance of key parameters relevant to understanding the nature of the opioid epidemic within their communities. These data should be drawn from medical, behavioral and criminal justice systems, and include, but not be limited to, measures such as: opioid and non-opioid analgesic prescribing, OUD treatment capacity, MOUD use and persistence, non-fatal and fatal opioid overdose events, naloxone distribution and use, criminal justice offense type, sentencing, treatment received while under court supervision (e.g., mandated treatment) and reoffending rates.
132. At a local level, such as within Cuyahoga and Summit Counties, there are many potential sources of data for these and other relevant measures.³¹ For example, clinical information can be derived from prescription drug monitoring programs and states' Health Information Exchanges (HIEs), emergency medical services and hospital and emergency administration data. Behavioral health data can be drawn from sources such as the minimum data sets that are directly collected by all Single State Authorities (e.g., state agencies on drug abuse) for specialty treatment programs and from Medicaid programs, as well as from sources such as the Drug Enforcement Agency's National Technical Information Service (NTIS) database of waived prescribers and state and federal databases on specialty treatment providers (e.g., the SAMHSA treatment locator which is updated annually and provides street addresses for treatment programs). Criminal justice data can be derived from states' Department of Corrections.
133. There is no question that the collection, curation, and integration of these data will require substantial cooperation, effort and tenacity on the part of local communities such as Cuyahoga and Summit Counties. Many of these data systems are maintained by different

³¹ While cities and counties should prioritize local high performance surveillance, resources are also needed for broader evidence repositories. Such repositories would allow for evaluation of interventions (e.g., naloxone distribution, treatment expansion) across diverse communities, strengthening opportunities for replication and dissemination of best practices.

private or public entities, and in some cases, significant administrative, legal and cultural barriers will have to be overcome. However, there is tremendous promise in such efforts, especially since the effects of the opioid epidemic, and remedies to abate it, extend across medical, behavioral and criminal justice systems. Linkage of these data will provide a more comprehensive understanding of the current issues associated with the epidemic and identify areas where local communities should focus.

134. For example, consider the case of policing, where public health oriented policing interventions, such as a focus on overdose deaths, use of naloxone, education regarding addiction and stigma, and treatment on demand, can play an important role in reducing opioid-related injuries and overdose deaths.³⁷⁷ Routine tracking of measures that evaluate that these and other approaches can be used for a number of purposes including to establish benchmarks, allocate resources, and evaluate the success of new initiatives with respect to process, such as how many doses of naloxone have been dispensed, and outcomes, such as how many overdoses have been reversed.
135. Surveillance must be combined with leadership such as has been demonstrated by individuals within Cuyahoga and Summit Counties. In other words, a cohesive, multidisciplinary team should coordinate a given community's response across multiple agencies, departments and stakeholders and based on a comprehensive needs assessment as outlined in Paragraphs #36-#37. Representation, and appropriate staffing, from key entities such as the medical, behavioral and criminal justice systems within the community is vital. The overall effectiveness of a community's response will rest in part upon the relationships among those coordinating the effort, and the overall coherence and shared vision among relevant parties. This team should meet regularly to review programs and policies, as well as assess surveillance data and emerging evidence from the field. In addition to serving as liaisons to their respective organizations, as well as more broadly championing the community's strategic response, the team should troubleshoot, redirecting resources and re-engineering how individuals with chronic pain, non-medical opioid use or OUD are identified and managed within relevant systems of care.
136. Abatement remedies in Cuyahoga and Summit Counties should include resources to support the development and management of a state-of-the-art surveillance program that can serve as a mission control center as remedies are deployed, iteratively refined and evaluated. Such resources should allow for relevant data from a variety of local, state and national sources to be gathered, curated and analysed, and in turn, reported back out using a variety of different approaches customized to the specific needs of key stakeholders such as public health officers, treatment providers and law enforcement officials. Remedies should also include resources to support the leadership that will be needed for a well-coordinated, longitudinal, multi-stakeholder initiative.

CATEGORY 3: CARING FOR SPECIAL POPULATIONS

Many groups of individuals have been uniquely affected by the epidemic, including pregnant women, children and adolescents and those who are incarcerated or otherwise enter the criminal justice system. Other marginalized or historically underrepresented groups, such as African Americans, Native Americans and Alaskan Natives, have also been impacted in unique ways. While some abatement remedies, such as naloxone distribution, generally need not be customized to specific subpopulations, there are other remedies that are important to design with specific populations in mind. The groups below are not intended to be exhaustive of special populations of interest, and in some communities or settings, other subpopulations may be important to consider as abatement remedies are deployed, ranging from women³⁷⁸ to those living in rural areas.³⁷⁹

CATEGORY 3A. INDIVIDUALS WITHIN CRIMINAL JUSTICE SYSTEM

One goal of this remedy is to increase the identification and treatment of individuals with opioid use disorder within the criminal justice system in both community and detention settings. This is important because the criminal justice system is a major thoroughfare for individuals with opioid addiction, and treatment of these individuals reduces their risk of overdose and recidivism while improving their societal reintegration. This remedy also focuses on other ways that the criminal justice system can positively impact the opioid epidemic through activities ranging from reducing stigma surrounding OUD to disrupting drug trafficking rings that are responsible for the distribution of illicit fentanyl.

137. The opioid epidemic has burdened the U.S. criminal justice system with a surge of inmates, increasing health care costs associated with OUD and producing high rates of overdose and recidivism. Data from the Department of Justice suggest over half of the incarcerated population has a substance use disorder,³⁸⁰ approximately one in four state prisoners between 2007-2009 reported prior heroin or opioid use,³⁸¹ and by some estimates, as many as one-fourth to one-third of individuals with heroin addiction are estimated to pass through the criminal justice system each year.³⁸² Fewer than 20% receive treatment,³⁸³ and what treatment is received is often inadequate. According to the Federal Bureau of Justice Assistance, as of August 2017, only 30 of the 5,100 (0.6%) prisons and jails in the U.S. offered opioid users methadone or buprenorphine,³⁸⁴ despite evidence that such treatment improves treatment entry and retention after release if arrangements exist to continue treatment.³⁸⁵ Because of this, detox facilities and access to MOUD, as well as other treatments along the continuum of care, are important for those incarcerated in jails, prisons or juvenile detention facilities. While such treatments should be made available to anyone with OUD, they are especially important for high priority populations such as pregnant women with OUD and individuals already on MOUD prior to incarceration.³⁸⁶

138. Drug courts. There is substantial evidence regarding the role that drug courts can play in diverting non-violent offenders from the criminal justice system to the treatment system, where their needs can be more effectively addressed.³⁸⁷ These programs represent special court dockets that provide judicially-supervised substance use treatment in lieu of

incarcerating individuals with drug-related offenses. The President's Commission on Combatting Drug Addiction and the Opioid Crisis included a recommendation that the "DOJ broadly establish federal drug courts within the federal district court system in all 93 federal judicial districts." Further, the Commission reported "States, local units of government, and Indian tribal governments should apply for drug court grants established by 34 U.S.C. § 10611. Individuals with a SUD who violate probation terms with substance use should be diverted into drug court, rather than prison."³⁸⁸ One of several sources of evidence to support the efficacy of drug courts is a comprehensive review commissioned by the U.S. Department of Justice that examined drug courts in the U.S.; the report, which was also supported by the Office of National Drug Control Policy (ONDCP) of the Executive Office of the President, found that the combination of comprehensive treatment services and individualized care provided by drug courts is an effective way to provide treatment to criminal offenders with substance use disorders.³⁸⁹ Both Cuyahoga County and Summit County have established drug courts. In Summit County, the majority of participants are opioid-dependent and yet capacity is limited.³⁹⁰

139. Interventions focused on law enforcement agents play a synergistic role to drug courts targeting criminal justice offenders. Law enforcement officers are in a key position to help reverse the opioid epidemic as they respond to overdoses and engage in community policing, a practice that places officers consistently in the same local settings to support their greater integration and partnership with community residents. Police departments in hard hit areas of the country have been stretched thin as they have attempted to devote sufficient resources to the opioid epidemic, which has in turn diminished their capacity to respond to other pressing needs within their communities. In addition to a pressing need for greater personnel, there are also specific law enforcement-related strategies that can equip officers responding to the opioid epidemic.
140. Training to reduce stigma. Since law enforcement officers are often the first responders to an overdose, they must have the training and confidence to appropriately respond.³² Such training, which should be repeated at regular intervals, may reduce stigma, increase the likelihood that individuals will call 911 for help and improve referrals for services and/or treatment. While not focused on opioid overdose per se, training for officers to reduce stigma related to behavioral health crises has been effective at improving officers' attitudes toward individuals with mental health issues^{391,392} and self-efficacy in handling these calls.³⁹³ Such Crisis Intervention Team (CIT) training has also reduced arrests and use of force³⁹⁴ and increased referrals for services during a mental or behavioral health crisis.^{395,396}
141. Law Enforcement Assisted Diversion (LEAD). LEAD is a program to divert individuals who would otherwise be arrested for drug-related charges into community-based services and/or treatment.³⁹⁷ LEAD is unique in that it occurs pre-booking so that if an individual who qualifies

³² Law enforcement officers within prisons and detention centers should also undergo similar training, given high rates of stigma in these settings as well.

for the program chooses to enroll, they do not have an arrest on their record if they complete program requirements. Qualifications are based on having committed a low-level drug offense and factors such as the amount of drugs possessed, absence of any intent to distribute and absence of disqualifying criminal history such as violent crime.³⁹⁸ Thus, in contrast to drug courts, LEAD participants never enter the criminal justice system and they are enrolled in LEAD instead of being charged with a crime. LEAD programs reflect partnerships between law enforcement and local behavioral health systems to enroll individuals in appropriate services. Seattle created the first LEAD program and early evaluation results suggest improved outcomes for participants including housing, employment, and reduced recidivism.^{399,400} As with Crisis Intervention Team training, law enforcement officers require training that should be repeated at regular intervals to maximize their familiarity and expertise with the conduct of LEAD.

142. Specialized overdose units. Some police departments have created specialized units to address the opioid epidemic. These units, such as one in Cleveland, Ohio,⁴⁰¹ are often comprised of detectives, sometimes within homicide or narcotics units, who work to link together overdose incidents across the city by identifying similar contacts, sources, dealers or other features between overdose events. These units treat sites of overdoses as crime scenes and work to track back to dealers and build cases for prosecution to bring down higher level supply sources for opioids.⁴⁰² The specific size and composition of these units, as with other components of an effective law enforcement response to the opioid epidemic, will depend upon many features of the local community, including the size and urbanicity of the jurisdiction as well as the burden of prescription opioids, heroin and illicit fentanyl.
143. Law enforcement plays a vital role in an effective response to the opioid epidemic, and any abatement program in Cuyahoga and Summit Counties should include resources to support each of these functions. While the specific needs of local law enforcement could extend beyond the areas identified above, at a minimum, resources should be committed to ensure that police departments are adequately staffed so that demands posed by the opioid epidemic can be fully addressed without detracting from an ability to address other areas of high local need. In addition, resources should be committed so as to staff and otherwise support prosecutors, drug courts,³³ training to reduce stigma for both community policing as well as among prison and detention center personnel, LEAD and, where required, specialized overdose law enforcement units. Resources are also required to support the development and management of detox units and treatment facilities within jails, prisons and detention centers so as to provide treatment access for individuals with opioid use disorder.

³³ For example, court systems in many communities need greater support to optimize their potential to connect individuals in need of treatment with ambulatory or intensive outpatient treatment. Thus, resources are needed for courts to sufficiently staff positions that allow for technical assistance to judges as well as increased tracking, case management, and coordination and integration of the activities of the court with each community's broader abatement approach.

CATEGORY 3B. CHILDREN, ADOLESCENTS AND YOUNG ADULTS

The goal of this remedy is to address the direct impact of opioid use, addiction and overdose on children, adolescents and young adults, including prevention programs that delay initiation or escalation of opioid use as well as screening and treatment programs that are customized to the unique needs of these special populations.

144. Children and adolescents are uniquely vulnerable to the consequences of non-medical opioid use, and as the opioid epidemic has flourished, many children and adolescents have been exposed. In 2005, approximately 10% of adolescents reported prior or current non-prescribed use of pain relievers.⁴⁰³ In 2015, an estimated 276,000 adolescents 12 to 17 years of age reported current nonmedical use of pain relievers with nearly half of these adolescents likely to be addicted to these products.⁴⁰⁴ Such use has occurred at high rates in Ohio, with 2013-2014 Summit County estimates that as many as one in eight (15.6%) of high school students reported non-medical prescription drug use (compared with state average of 12.8%) and an estimated 4.1% of high school students reported prior heroin use, twice as much as the state's (2.0%) and national (2.2%) average.⁴⁰⁵ Fortunately, there is evidence that opioid misuse among children and adolescents has declined somewhat over time. Past-year misuse of Oxycontin among high school seniors has declined from 5.5% (2005) to 2.7% (2017), while the proportion of high school seniors reporting prescription opioids as easily accessible has declined from 54% (2010) to 36% (2017).⁴⁰⁶ Despite this, the fact that one-third of high school seniors in 2017 reported that opioids are easy to obtain suggests their continued oversupply and remains of great concern.
145. The American Society of Addiction Medicine recognizes adolescents, individuals 11-21 years of age, as a special population of interest with respect to substance use disorders.⁴⁰⁷ Not only has early initiation of drug use been strongly associated with a constellation of adverse consequences, such as poor peer and familial relationships and entanglements with the juvenile justice system,⁴⁰⁸ but the ongoing brain development in adolescents during this period of time make them highly vulnerable to substance use disorders.⁴⁰⁹ Because of their vulnerability and future potential, prevention and early detection of substance use disorders in youths should be heavily prioritized to minimize the short- and long-term consequences associated with drug use at an early age.
146. Several school-based or family-based prevention programs have successfully delayed initiation or escalation of drug use in youths.^{410,411,412} For example, the Life Skills Training (LST), a widely used school-based module, has been demonstrated in several controlled studies to reduce substance use amongst adolescents.⁴¹³ The impact of LST may be enhanced when coupled with the Strengthening Families Program (SFP), a family-based intervention designed to develop and support family bonds and communication. Greater investment should be made in the continued dissemination, implementation and evaluation of these and other evidence-based programs that are focused on primary prevention through education of broad populations regarding the nature of opioid use disorder, risks of non-medical use and availability of treatment and recovery supports.

147. Treatment for adolescents with substance use disorder requires a unique approach and should be delivered by individuals with specialized training in the care of this population. For example, unlike older adults who have often spent years coping with substance use accompanied by a deterioration in psychosocial domains (e.g., loss of job or family), adolescent users tend to present at treatment after only a few years of addiction. In contrast to adults with substance use disorders, adolescents' drug use is often driven by different factors (e.g., familial discord), may be subject to different environmental influences (e.g., peer effects) and may compromise psychological development.⁴¹⁴
148. Use of MOUD is recommended for adolescents with severe opioid use disorders. Buprenorphine and naltrexone may provide more suitable treatments for adolescents than methadone, since these can be administered in office-based treatment settings. Furthermore, one of several evidence-based psychosocial therapies should be used simultaneously with MOUD when treating adolescents with substance use disorders. One type of psychosocial therapy is family-based therapy, which aims to reduce the adolescent's drug use by involving the youth's family members in the treatment process. This mode of therapy facilitates the development of emotional support and communication strategies in order to address issues such as antisocial behavior or dysfunctional family interactions.
149. Abatement remedies in Cuyahoga and Summit Counties should include resources to reach at risk children and adolescents through school and community-based youth programs. In addition to screening and primary prevention programs to teach and reinforce positive life skills, resources should also be committed to the care of children and adolescents with opioid use disorder, which may require expansion of personnel with customized expertise in this area, as well as resources to support the expansion of both pharmacologic and non-pharmacologic treatment and recovery services.

CATEGORY 3C. CHILDREN IN FOSTER CARE AND CHILD PROTECTIVE SERVICES

The goal of this remedy is to improve the resources available to support children who have been orphaned by the epidemic, as well as to assist children and their families who have otherwise been impacted and who may be served through child protective services.

150. The opioid epidemic has severely impacted many families, and at times, forced children to be separated from parents and placed in foster care. In 2017, there were nearly 443,000 children in foster care in the U.S., an increase of 46,000 children since 2012.⁴¹⁵ Much of this increase is attributable to the opioid epidemic.⁴¹⁶ Of the 273,000 children that entered foster care 2016, over 92,000 (34%) children were placed in out-of-home care and parental substance use was reported as a factor in the reason for removal.⁴¹⁷ However, states vary in reporting on this variable and these data are considered an undercount of the prevalence of substance use among child welfare cases.^{418,419,420} Vastly more children – as many as one in eight – live in a household with one or more parents who have a history of past year substance use disorder.⁴²¹

151. While the precise number of these placements that were directly due to opioids is unknown, a recent mixed-methods study commissioned by the U.S. Department of Health and Human Services provides additional context.⁴²² Geographic regions of the country with higher rates of overdose deaths and drug-related hospitalizations also have higher child welfare caseloads, as well as more severe and complex child welfare cases. In addition, many key informants reported worsening conditions, such as overdose deaths and caseload numbers, between 2015 to 2017. The report also identified many barriers to treatment of impacted families, including misunderstanding and mistrust of MOUD, piecemeal substance use assessments, shortages of family-friendly treatment and an increasing shortage of foster care homes. The report concluded that while these findings may not represent every geographic region or state, they nevertheless suggest how the opioid crisis has taken an unusual toll on an already strained child welfare system.
152. Children entering the foster care system, including those whose entry has been driven by the opioid epidemic, have both medical and non-medical needs. Federal and state governments often provide support to guardians of foster children for non-medical needs such as food, clothing and housing. Many children in foster care also have special health care needs, given the high prevalence of chronic medical, developmental, and mental health problems, most of which predate placement in foster care.⁴²³ Lastly, approximately 21-23% of children exiting foster care are adopted.⁴²⁴ Though some adoption costs are offset with government subsidies, the adoption process can nevertheless impose a heavy economic burden on some families.
153. Child protective services (CPS) includes a variety of interventions that are undertaken by state agencies charged with optimizing the health and welfare of otherwise vulnerable infants, children and adolescents. Such services include the investigation of reports of child abuse or neglect as well as the delivery of services, such as specialized case management and multisystemic or other family-based therapy, to support children and families where abuse or neglect has taken place or is likely. CPS is based on several underlying principles including a recognition that a safe and permanent home is the best location for children to be raised and that most parents want to be good parents to their children.⁴²⁵ Summit County Children Services has served as one of 11 pilot counties for the Ohio Statewide System Reform Project (SSRP); they operate a family treatment court and have also implemented a universal screening tool which seeks to identify families and parents impacted by substance abuse disorders.⁴²⁶ Identification of parents and guardians who may have opioid misuse or OUD presents opportunities to connect them to needed treatment services. Summit County has also offered family drug assessments, recovery coaches, substance abuse treatment through local providers, and other related services under the STARS Program until the federal grant that funded the program ended.^{427,428} Cuyahoga County offers similar services for birth mothers who test positive for drugs or alcohol through the START program.⁴²⁹
154. Any abatement program in Cuyahoga and Summit Counties should include resources to support the needs of children who have been orphaned by the epidemic or who have lost a parent, whether or not they have entered the foster care system. In addition, abatement

remedies should include resources, including intensive case management and access to therapy, to support the needs of children and adolescents who may have entered child protective services or otherwise come to the attention of social services organizations within the affected communities.

CATEGORY 3D. PREGNANT WOMEN AND NEONATES

This abatement remedy focuses on pregnant women who have chronic opioid dependence, opioid misuse or OUD, as well as infants born with neonatal opioid withdrawal syndrome (NOWS), a condition among newborns that is a consequence of in utero exposure to opioids.³⁴ (NOWS is also sometimes referred to Neonatal Abstinence Syndrome, although the latter is a less specific term that may refer to in utero exposure to other substances such as alcohol or tobacco.) As with other special populations such as children and adolescents, pregnant women and their newborns are important to consider because of the ways that abatement remedies should be designed to address their unique needs and vulnerabilities.

155. The opioid epidemic has severely impacted pregnant women and neonates. Approximately 15% of commercially insured women and 22% of women on Medicaid filled an opioid prescription during their pregnancy.^{430,431} The rate of NOWS, a condition associated with utero exposure to opioids, has also increased as opioid prescribing has increased. For example, in an analysis of hospital discharges from 2009 to 2012, the estimated rate of NOWS increased from 3.4 to 5.8 per 1000 hospital births.⁴³² A longer time horizon provides similar evidence, with estimates of the diagnosis of NOWS increasing from 1.2 to 8.0 live births between 2000 and 2014; during this time period, some states experienced as large as a ten-fold increase.⁴³³
156. Both the Substance Abuse and Mental Health Services Administration (SAMSHA) and the American College of Obstetricians and Gynecologists (ACOG) have provided similar recommendations for targeting and treating pregnant women and neonates impacted by the opioid epidemic, including with respect to prenatal screening for opioid use among women who are pregnant, MOUD treatment for pregnant women with opioid use disorder, neonatal care for neonates born with NOWS, and residential transition programs for pregnant women and new mothers with OUD who have limited social supports.^{434,435}
157. Prenatal screening. SAMSHA and ACOG strongly recommend screening pregnant women for substance use disorders including OUD. ACOG specifically recommends universal screening as part of obstetric prenatal care visits, and both suggest using validated screening tools such as the National Institute on Drug Abuse's (NIDA's) Quick Screen or Substance Use Risk Profile–Pregnancy (SURP-P).⁴³⁶ Both organizations also suggest screening be part of a Screening, Brief Intervention, and Referral to Treatment (SBIRT) approach, although concerns

³⁴ NOWS has also been historically referred to using the less specific term "neonatal abstinence syndrome (NAS)" which may refer to infant in utero exposure to other medicines or substances such as tobacco or alcohol.

with SBIRT as it applies to opioids have been raised. For example, some SBIRT studies have been negative and the effect in positive studies often modest. In addition, SBIRT is predicated upon the availability of follow-up treatment and the motivation of the individual to seek it, and the “brief intervention” of SBIRT was designed for behavioral treatments, which overlooks FDA-approved pharmacotherapies for OUD.³⁵ Because of this, Screening, Treatment Initiation and Referral (STIR) has been proposed,⁴³⁷ and demonstrated to achieve better outcomes than SBIRT in at least two randomized trials, one focused on tobacco dependence⁴³⁸ and the other on OUD.⁴³⁹ The decision to initiate MOUD upon an index visit, as compared with referral for follow-up care, should be informed by a number of factors, including the context of the visit, stability and preferences of the patient, and availability and likelihood of suitable follow-up.

158. MOUD treatment. SAMSHA and ACOG suggest pregnant women with OUD be treated with MOUD. This is partly due to concerns that other treatment approaches (e.g., abstinence) pose an increased risk of fetal injury or demise. MOUD treatment should focus on the provision of buprenorphine and methadone, rather than naltrexone, since there is less information on how naltrexone may impact fetal development.
159. Neonatal care. NOWS refers to the presentation of withdrawal symptoms amongst infants who have been exposed in utero to opioids. Expression of NOWS is widely variable, though long-term complications may include poor neurological and motor development.⁴⁴⁰ Infants at risk of presenting with NOWS may require specialized care such hospitalization within a neonatal intensive care unit.
160. Residential transition programs. Pregnant women and new mothers also need stable environments for their own health, their baby’s health, and the best chance for positive treatment outcomes. A stable environment includes long-term housing, child-care, access to transportation, all within a family-oriented and supportive environment. Some pregnant women with OUD will require residential treatment because of limited economic capital and/or serious medical illness or behavioral health needs.
161. Any abatement program in Cuyahoga and Summit counties should include resources for pregnant women and neonates impacted by the epidemic. Such resources should include: services to identify and treat pregnant women with OUD as early as possible; longitudinal services to support women and address modifiable risk factors throughout their pregnancy; clinical and behavioral interventions in the peri- and post-partum period; hospital and child welfare resources to comply with the Child Abuse Prevention and Treatment Act to ensure a plan of safe care is implemented for the infant and family or caregiver before the infant is discharged from the hospital; and follow-up services to optimize care for the mother-child

³⁵ For example, some SBIRT studies have been negative and the effect in positive studies often modest. SBIRT is predicated upon the availability of follow-up treatment and motivation of the individual to seek it and the “brief intervention” of SBIRT was designed for behavioral treatments, which overlooks FDA-approved pharmacotherapies for OUD.

dyad following hospital discharge, including the required developmental assessment for early intervention if the child is placed in out-of-home care.

CATEGORY 3E. AFRICAN AMERICANS, AMERICAN INDIANS AND ALASKAN NATIVES

This abatement category focuses on the unique needs of African Americans, American Indians and Alaskan Natives (AIAN's). This remedy is important because the opioid epidemic is typically portrayed as impacting young and middle-aged, working class, suburban and rural whites. However, African Americans and AIAN's have not only been historically disenfranchised but also in some areas have been disproportionately impacted by the opioid crisis.

162. There is a long history of race intersecting with the issue of substance use disorder in America. As the historian David Courtwright has noted, "what we think about addiction [in America] depends very much on who is addicted".⁴⁴¹ Ironically, African Americans have been spared from some of the harms associated with prescription opioids because of racial and ethnic disparities in the treatment of pain, such that compared with Whites Americans, Black Americans are less likely to receive prescription opioids for pain.^{442,443} On the other hand, among individuals on long-term opioid treatment for chronic pain, prescribers are significantly more likely to discontinue such treatment based on a positive screen for illicit drug use (e.g., cannabis) among Black Americans than White Americans.⁴⁴⁴
163. There are many pathways where racial/ethnic bias may affect the clinical treatments that patients ultimately receive, ranging from stereotypes regarding pain thresholds of racial/ethnic minorities and their counterparts to different expectations regarding whether and how quickly pain resolution should be achieved. In addition, more systemic barriers contribute to the high rate of injuries and deaths from opioids among African Americans and AIAN's in some communities, ranging from housing to education to health care access, and thus just as with other racial and ethnic disparities in care, these are important to consider and address as interventions are designed to focus around prevention, treatment and recovery.^{445,446}
164. It is true that nationally, the mortality rate from opioids among African Americans has been lower than that of White Americans.⁴⁴⁷ For example, in 2016, the national rate of fatal opioid overdose was 17.5 per 100K among non-Hispanic whites as compared with 10.3 among non-Hispanic blacks. However, in some states, African Americans are dying at higher rates than their counterparts.⁴⁴⁸ In Ohio, while 2017 overdoses were greatest among non-Hispanic whites (42.8), even among non-Hispanic blacks overdoses were alarmingly above the national rate (33.3).⁴⁴⁹ Because of their historic marginalization, the impact of the opioid epidemic on African Americans within Cuyahoga and Summit Counties and other communities should be explicitly considered while designing interventions focused to support prevention, treatment and recovery. For example, policies that differentiate or focus on supporting those with prescription opioid addiction while instituting punitive approaches against those who use heroin or illicit fentanyl may disenfranchise African Americans, just as different criminal penalties for crack and powdered cocaine did in the 1980's and 1990's.⁴⁵⁰

165. Mortality from drug overdoses of any kind among AIAN's is also disproportionately high. For example, between 1999 and 2010, AIAN populations had a mortality rate of 17.1 per 100,000 compared to 16.6 in white, non-Hispanic populations and 8.9 in black, non-Hispanic populations and 5.5 in Hispanic populations.⁴⁵¹ That renders their mortality from drug-induced deaths the highest of any ethnic group in the United States. From 1999-2015, AIANs also experienced the largest percentage change increase in the number of deaths over time, up to 519% in nonmetropolitan areas.⁴⁵²
166. In 2016, the national rate of fatal opioid overdose was 13.9 per 100K for non-Hispanic AIAN.⁴⁵³ Furthermore, SAMSHA's Tribal Technical Advisory Committee notes that determining universal rates and risks of substances misuse is challenging due to the diversity and geographical dispersion of AIAN population, resulting in varied estimates across different regions and tribes. For example, for the states of Idaho, Oregon, and Washington, the Northwest Portland Area Indian Health Board reported that from 2006 to 2012, of drug overdose deaths, 65.3% of AIAN deaths were from prescription drugs, and of those, 77.2% were from opioids.⁴⁵⁴ AIAN adolescents have also been affected quite heavily, with estimated 2012 rates of non-medical use of prescription opioids twice as high as that of non-Hispanic whites and three times as high as that of African Americans.⁴⁵⁵ Furthermore, though most (71%) AIAN populations live in rural, urban and suburban areas,⁴⁵⁶ only ~2% of IHS funding is used to support urban Indian health clinics.⁴⁵⁷ As with African Americans and as noted in Paragraph #163, AIAN populations are also more vulnerable to risk factors that increase the risk of both OUD as well as mortality, such as poverty, unemployment and alcoholism.⁴⁵⁸
167. Not only has the opioid epidemic resulted in high morbidity and mortality among AIAN populations, but it also has affected tribal communities in unique ways. For example, such communities face persistent funding challenges, and community members are inhibited from seeking services due to geographic distances and staffing concerns.⁴⁵⁹ Further, Western treatment programs, including MOUD, may be incongruent with traditional healing practices, beliefs and ideas,⁴⁶⁰ and specialty services and types of medical care that are not available at a given facility are often purchased from the private sector through a contract health service (CHS) program, which applies a stringent eligibility criteria to determine which patients qualify for CHS funding.⁴⁶¹ Efforts to alleviate the crisis are underway, with the IHS' implementation of the RPMS Report and Information Processor (RRIP) program⁴⁶² to monitor opioid prescribing, as well as initiatives for provider education and increased accessibility to naloxone and medication-assisted treatment in partnership with the Bureau of Indian Affairs.⁴⁶³ However, in many AIAN communities, greater resources to support a more comprehensive and sustained abatement program are urgently needed.⁴⁶⁴
168. While AIAN are important to consider in many parts of the United States, they are not heavily represented in Cuyahoga and Summit Counties. For example, Cuyahoga County is 30.5% African American and 0.3% Native American, while Summit County is 15.0% African American and 0.2% AIAN.⁴⁶⁵ In addition, the State of Ohio does not have any federally or state recognized tribes.⁴⁶⁶ Thus, while there are many parts of the United States where tribal

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communities are essential to consider as a special population with respect to opioid abatement, in Cuyahoga and Summit Counties, African Americans are much more prevalent and impacted.

169. Because of this, as abatement remedies are developed in Cuyahoga and Summit Counties, it is important to consider how they can be deployed so as to equally serve African Americans as their counterparts. This includes assessing whether and how, at least inadvertently, remedies may further marginalize or stigmatize African Americans with opioid misuse or OUD. For example, if non-African Americans with OUD are predominantly treated with buprenorphine while African Americans are predominantly treated with methadone, a program that expands buprenorphine at the expense of methadone could inadvertently widen racial and ethnic disparities in MOUD uptake. Similar considerations should be given to other abatement remedies as they are designed, deployed and evaluated, ranging from media campaigns (e.g., "Is messaging designed so as to appeal to African American communities impacted by the epidemic?") to interventions within the criminal justice system (e.g., "Are drug courts being used in ways that equitably support opportunities for societal integration of all individuals regardless of their race or ethnicity?").

CATEGORY 3F. INDIVIDUALS WITH OPIOID MISUSE

This abatement remedy focuses on individuals who misuse opioids. This category is important because there are millions of Americans who engage in such misuse, and they are at elevated risk for a number of harms from opioids, including the development of opioid use disorder and overdose death.

170. Opioid misuse is defined by the National Institute on Drug Abuse (NIDA) as "taking a medication in a manner or dose other than prescribed; taking someone else's prescription, even if for a legitimate medical complaint such as pain; or taking a medication to feel euphoria (i.e., to get high)".⁴⁶⁷ In contrast to opioid use disorder, which has formal diagnostic criteria according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), opioid misuse is more common and encompasses a broader continuum of behaviors. It is important to identify individuals with opioid misuse because they are at increased risk of opioid-related adverse events.
171. An estimated 11.4 million Americans, or 4.2% of the total population, reported misuse of prescription opioids or heroin during the past year based on 2017 data derived from the National Survey of Drug Use and Health (NSDUH).⁴⁶⁸ While this represents a modest decline from 2015, during which 12.7 million people were estimated to have engaged in past year opioid misuse, the numbers nevertheless remain staggering. Of these 11.4 million individuals, 97.2% engaged in past year misuse of prescription opioids, while 7.8% engaged in misuse of heroin and 4.9% engaged in misuse of both prescription opioids and heroin. Among adults who misused opioids in 2015 who did not have an OUD, approximately two-thirds of cases reported the reason for such misuse was the relief of pain, highlighting the overlap of chronic

pain with non-medical opioid use as well as the opportunities to address both simultaneously through well-designed abatement remedies.⁴⁶⁹

172. As many as one-third of individuals misusing opioids report that the source of their opioids was a single prescriber,⁴⁷⁰ an indication that the health care system, including high prescribing clinicians, continues to play a role in fostering the epidemic.³⁶ By contrast, more than one-half of those misusing opioids report their source as a friend or relative, a reminder of the continued diversion of opioids that also commonly occurs, although here too, the most common source of opioids among these friends or family members remains a licensed prescriber.⁴⁷¹ The large oversupply of opioids in these settings supports the use of interventions such as prescription “caps” that states and some payers are increasingly using to reduce the volume of opioids prescribed for short-term use,⁴⁷² as do several studies indicating that the likelihood of an individual converting to chronic opioid use is significantly greater among individuals receiving greater doses or durations of opioids on their first fills.^{473,474,475}
173. In contrast to patients who are using opioids fully as directed under the care of a licensed prescriber, which still poses unacceptably high risks in many patients currently receiving them, patients with opioid misuse should be identified and targeted for early intervention so as to avert their potential transition to opioid use disorder or overdose. Methods to identify and address these patients include both the routine clinical use of prescription drug monitoring program (PDMP) data and clinical interviewing. Clinical interviewing is useful not only to screen for potential misuse but also to explore motivations for such and to address underlying issues, including sub-optimally treated pain, depression or other behavioral health factors that may be driving such behavior. Once identified, such patients should receive more intensive clinical monitoring, psychosocial interventions, pain management, and in some cases, transition to partial opioid agonists such as tramadol.
174. Any abatement program in Cuyahoga and Summit Counties should include resources devoted to addressing the substantial minority of individuals who misuse opioids. Clinicians should be trained to routinely evaluate patients for such practices, OARRS data should be increasingly integrated within health systems and electronic medical records, and interventions should be deployed to decrease the volume of opioids prescribed, which in turn will decrease the incidence of misuse. Once opioid misuse has been identified, greater clinical resources should be devoted both to addressing opioid misuse directly as well as evaluating and treating potential contributory factors ranging from comorbid social stressors or mental illness to untreated or undertreated chronic pain syndromes.

³⁶ By contrast, 1.5% of those with opioid misuse report their source as from more than one doctor, again attesting to the relatively small contribution opioid shoppers make to the epidemic (see Paragraph #33).

ESTIMATING NATIONAL COSTS OF ABATEMENT

175. As I note in Paragraph #20, in addition to human suffering and loss of life, addressing the opioid epidemic will require significant economic investments. While the exact costs of abatement are difficult to estimate, and will depend upon the population requiring services and the programs in existence in each jurisdiction, it is possible to estimate the cost, nationally, of the efforts required to reduce further harms. These costs can then be "mapped" into Cuyahoga and Summit counties, based upon existing needs and resources. Estimating abatement costs can also help to identify how the need for investments may vary based on how the epidemic evolves.³⁷
176. I performed preliminary analyses of the national costs of fifteen types of remedies (Table).³⁸ My goal was not to identify the precise costs of any given category, but rather to develop an initial estimate from which costs specific to Cuyahoga and Summit County can be developed based on this Court's findings with regard to the nuisance in these jurisdictions.

Table. Preliminary National Estimates of 10-year Costs of Different Abatement Remedies.		
ABATEMENT CATEGORY	COMPONENTS	10-YEAR COST (\$ BILLIONS)
1. Medication Assisted Treatment	Medication and infrastructure	\$170.4
2. Criminal Justice Interventions	Drug courts; post-incarceration housing and counseling	\$35.1
3. Mass Media Campaign	Mass media campaign	\$5.7
4. Naloxone	Improved naloxone access	\$9.1
5. Adolescent Interventions	Prevention; screening and intervention	\$17.8
6. Academic Detailing	Peer outreach to prescribers, EMTs, dispensers	\$2.1
7. Pregnant Women/Neonates	Screening and housing for pregnant women, NAS treatment	\$17.9
8. Foster Care Interventions	Medical and non-medical care; adoption costs; CPS	\$37.3
9. Hepatitis C/HIV Interventions	Screening and treatment for Hepatitis C/HIV	\$31.3
10. Drug Disposal Programs	Infrastructure and execution of drug disposal programs	\$11.1
11. Surveillance	National surveillance programs for OUD; overdose	\$2.2
12. Harm Reduction Interventions	SSPs; supervised consumption facilities; fentanyl testing strips	\$25.3
13. PDMPs	Maintenance and improvement of PDMPs	\$0.7
14. Research	Funding for safer & more effective pain and OUD treatment	\$13.0
15. Law Enforcement Interventions	LEAD Programs, Overdose Units, Anti-Stigma Training	\$43.5
TOTAL		\$422.5
EMT = Emergency Medical Technician; NAS = Neonatal Abstinence Syndrome; HIV = Human Immunodeficiency Virus; CPS = Child Protective Services; OUD = Opioid Use Disorder; SSP = Syringe Services Programs; PDMPs = Prescription Drug Monitoring Programs; LEAD = Law Enforcement Assisted Diversion		

177. My general approach consisted of four steps:

- 1) First, I identified the potential components for each category, estimated the unit costs based on published literature, primary data sources and budgets of existing programs (e.g. per diem, per patient, etc.);
- 2) Second, I applied assumptions for a "ramp-up" period and the inclusion of indirect costs, such as infrastructure that will be required for treatment expansion in some communities;

³⁷ For example, required investments in treatment for opioid use disorder will depend upon the population of individuals with OUD over time, which in turn may be affected by whether or not the oversupply of opioids can be effectively diminished.

³⁸ While many communities will ultimately need to develop local estimates, these national estimates may nevertheless be of interest both with respect to methodology as well as the estimates derived.

- 3) Third, I modeled costs for ten years (2019-2028) with inflation, without a discount rate on the expectation that money would be paid out over time;
 - 4) Finally, I applied unit costs to a "target" population based on: (1) the current baseline population of affected individuals; and (2) estimated changes in the relevant population over time.³⁹ I derived these populations from the economic model ("Markov model") described in Paragraph #13.
178. For example, to calculate the ten-year treatment costs for OUD, which represented the largest abatement category, I derived estimates of the cost of MOUD from published cost-effectiveness analyses^{476,477} and the National Average Drug Acquisition Cost⁴⁷⁸, estimated infrastructure costs from the published literature^{479,480}, assumed an equal mix of the three FDA-approved products as a base case⁴⁰, and incorporated provider treatment costs, also from the peer-reviewed literature. Estimates of the population of individuals with OUD requiring such treatments over ten years were derived from the Markov model, and multiplied by the estimated treatment costs.⁴¹
179. For some categories, specific costs will depend upon decisions made by the Court or its designees, local policy-makers and service providers based on the mix of products and services used in the Counties and the manner in which those products and services are procured. In just one area, for example, the cost of naloxone will depend upon:
- the most likely use of different formulations (e.g. Narcan® vs Evzio®)
 - how future product innovation will affect their prices
 - whether there are other distribution channels beyond those proposed in Paragraph #112
 - whether discounts are available to the purchaser
 - how future changes in the opioid epidemic will impact the need for naloxone.
180. Ultimately, detailed assessments of the specific costs within Cuyahoga and Summit Counties will be required, and there are a number of limitations in extrapolating from national estimates to specific localities. Nevertheless, using 2017 opioid overdoses as one proxy for global abatement needs from the epidemic, these counties accounted for approximately 1.50% of national overdose deaths⁴⁸¹ (524 opioid deaths in Cuyahoga County and 190 deaths in Summit County/47,600 national opioid overdose deaths⁴⁸²), which would represent approximately \$6.34 billion dollars of the total figure depicted in the Table over ten years (1.50% X \$422.5 billion).

³⁹ Some of the interventions (e.g., mass media campaign, surveillance) were applied against a constant population, assuming that no reduction in these investments would occur over the observation period, although sensitivity analyses modifying these assumptions can be performed.

⁴⁰ Data on MOUD suggests such an assumption substantially overestimates naltrexone and underestimates buprenorphine use, changes that the model can easily accommodate.

⁴¹ Note that while these estimates included the costs of MOUD for pregnant women with OUD as well as for those needing treatment within the criminal justice system, the costs did not incorporate the additional health care costs of those with OUD who are not on stable MOUD, which could substantially increase the estimated costs of this category.

181. My analyses do not address how abatement costs should be shared across different parties. In addition, some (e.g., "Medication Assisted Treatment"), but not all, of my estimates exclude costs arising from individuals with heroin use disorders without prior prescription opioid use. These national estimates may be useful as local communities, including Cuyahoga and Summit Counties, map the resources they have committed or available, as well as estimate future costs of their own abatement programs. For example, my model inputs, structure and outputs may all be useful for communities to consider and compare against their own, when available. While the costs depicted in the Table are considerable, they remain a fraction of the costs of the epidemic, and as discussed in Paragraph #93, the individual and societal return on investment for interventions such as treatment for OUD is clear.

POTENTIAL OBJECTIONS TO PROPOSED ABATEMENT REMEDIES

There is remarkable consensus among public health experts regarding the abatement remedies outlined above, because they rest upon a large evidence-base, and thus action can be informed by evidence.⁴² Nevertheless, some might object to one or more of the proposed remedies on a number of grounds.⁴³

182. Enough is already being done. One argument is that there is already an enormous amount of effort being devoted to the epidemic, as well as some signs that things are "turning around". For example, prescription opioid volume continues to decline, there have been large reductions in overdoses in some communities, there are open treatment beds in others, and national awareness of the gravity of the epidemic is growing. While such arguments might have some appeal, they overlook the complexity of the epidemic, continued evidence of grave harms and the fact that investments made thus far reflect a small fraction of the epidemic's societal costs. For example, despite declines in opioid sales, prescribing rates remain far above pre-epidemic baselines. Similarly, while overdoses have declined in some communities, in others they remain higher than ever before, and there is no indication that flow of fentanyl into the country has been stopped. As noted in Paragraph #86 and elsewhere herein, there are vast gaps that remain in the treatment system, and many of the most damaging consequences of the epidemic, such as its effects on children, families and those with active addiction or a history of OUD, will endure for generations.
183. Further research is needed. Theoretically, it would be of interest to have randomized experiments assessing the effectiveness, and comparative effectiveness, of different interventions to reduce opioid-related morbidity and mortality. However, such investigations are impractical, and often, unethical as well.⁴⁸³ As a result, policy-makers and other

⁴² As noted in Paragraph #118, some policy-makers have sounded alarm regarding harm reduction approaches and supported more punitive enforcement policies, but there is little to no debate among public health experts regarding these matters, and any disagreement is dwarfed by the amount of scientific consensus regarding broad approaches to prevention, treatment and recovery as outlined above.

⁴³ Yet an additional objection, that the primary problem is one of heroin and illicit fentanyl, not prescription opioids, is addressed in Paragraph #34.

stakeholders must rely upon observational evidence that is prone to shortcomings. For example, the effect of an intervention such as a naloxone law may be delayed, obfuscated by other contemporaneous policy changes, or associated with unintended effects that diminish its ultimate welfare impact. These challenges underscore the importance of continued study by clinicians and public health experts, as well as investments such as the National Institutes of Health HEAL Initiative.⁴⁸⁴ While it will always be the case that “further research is needed”, particularly regarding some abatement approaches, there is already a large amount of information about many facets of the epidemic, and, as already noted, “the cost of doing nothing is not nothing”.⁴⁸⁵ For example, there is unequivocal evidence of the benefits of treatment with MOUD, as of enormous gaps in its accessibility and provision for individuals with opioid use disorder. This overwhelming evidence explains the strong scientific consensus regarding the importance of expanding the treatment system, as well as many of the other abatement remedies discussed herein.

184. There may be unintended consequences. As noted in Paragraph #29 and Paragraph #34, concern has been raised regarding potential unintended consequences of efforts to address the epidemic, especially “supply-sided” interventions such as clinical guidelines that may reduce the volume of opioids used in clinical practice. It is theoretically possible that reductions in opioid prescribing may pose a burden on individuals in whom opioids are clinically appropriate, and thus the importance of multifaceted approaches to diminish this likelihood, including: investments in pain research; continued evidence generation and synthesis such as the activities undertaken by the CDC and professional societies, provider and patient education; insurance coverage and benefit redesign; and surveillance. Similarly, while arguments that constraining opioid oversupply “just pushes people to heroin” are over simplified,⁴⁴ such concerns underscore the urgency of expansions in the treatment system to accompany supply-sided interventions reducing the flow of people from the general population into opioid use disorder.
185. We shouldn’t reward bad behavior. Variations on this argument include that people who are “running into trouble” should know better, or more abhorrently still, “three strikes and you are out”.⁴⁵ These approaches to managing the opioid epidemic blame the victims and reflect classic stigmatizing language grounded in erroneous beliefs regarding the nature of addiction. No one chooses addiction any more than one chooses to have colon cancer or multiple sclerosis.⁴⁸⁶ Such language overlooks this and conflates abuse, which is a behavior, with addiction, which is a disease. It also is hard to reconcile with the fact that, as established in the expert report by Katherine Keyes, the majority of individuals with opioid use disorder developed it through receipt of opioids from the health care system. It is precisely this type

⁴⁴ There is not a zero-sum game between reducing prescription opioid oversupply and increasing heroin use. For example, see Compton WM, Jones CM, Baldwin GT. Relationship between Nonmedical Prescription-Opioid Use and Heroin Use. *N Engl J Med*. 2016;374:154-63.

⁴⁵ Such an argument was proposed by a city council member in a small town in Ohio, who argued that the use of Emergency Medical Services should be restricted among people who utilize such services for multiple opioid overdoses.

of language, and persistent stereotypes regarding the nature of opioid dependence, misuse and addiction, that have slowed progress in addressing the epidemic over two decades, and that should be aggressively rebutted head-on as part of campaigns to educate the general public and health care providers regarding the nature of the epidemic.

186. MOUD isn't that effective and it is diverted. In fact, there is a substantial body of evidence regarding the effectiveness of treatments such as buprenorphine and methadone in retaining people in treatment, reducing illicit drug use, decreasing criminal activity and preventing overdose death.^{487,488} It is true that relapse among people with OUD is not uncommon, just as is the case with cancer, depression and many other chronic diseases. Similarly, while treatment failures occur with MOUD, the empiric response rate to many medicines (e.g., antidepressants) is low, but this does not obviate their potential clinical and public health value. An overwhelming amount of evidence indicates that MOUD can significantly decrease mortality and other undesirable outcomes, a reduction that could be seldom matched by treatments for many other chronic diseases. Nonetheless, diversion of MOUD remains a concern, and underscores the importance of greater, rather than fewer, investments in the treatment system to enhance the comprehensiveness and continuity of individuals seeking care for addiction.⁴⁶

CONCLUSION

187. The opioid epidemic is the worst drug epidemic in our nation's history, and it has been driven by large increases in the oversupply of prescription opioids for the treatment of pain. While all measures of the epidemic, from prescription opioid sales to rates of addiction to overdose deaths, remain at alarming levels, there is increasing recognition of the magnitude of the harms that have accrued, and remarkable scientific and public health consensus regarding what needs to be done. The abatement remedies described herein represent evidence-based and evidence-informed approaches that many communities have already begun to undertake with varying degrees of coordination and scale, and they are highly aligned with the three principles described at the outset of this report: (1) informing action with evidence; (2) intervening comprehensively; and (3) improving the care of those with pain. There is no single template for how these interventions should be combined and deployed in communities across the country, although their impact will be greatest when based on a comprehensive needs assessment as proposed herein for Cuyahoga and Summit Counties. As the citizens and leaders of those counties know all too well, there is not a moment to lose.

⁴⁶ The use of directly observed therapy (DOT) to deliver methadone, and provider administered buprenorphine formulations, are both additional means of reducing potential MOUD diversion.

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February 2019

CURRICULUM VITAE
G. Caleb Alexander, MD, MS

PERSONAL DATA

Business Address

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Center for Drug Safety and Effectiveness
Department of Epidemiology
615 N. Wolfe Street W6035
Baltimore, MD 21205
Phone: 410 955 8168
Fax: 410 955 0863
Email: galexand@jhsph.edu

Clinical Address

Johns Hopkins at Green Spring Station
10753 Falls Road Suite 325
Lutherville, MD 21093
Clinic Phone: 410 583 2926
Clinic Fax: 410 583 2883

EDUCATION AND TRAINING

1988-1990	Candidate for BA, Oberlin College
1991-1993	University of Pennsylvania, BA (Philosophy)
1994-1998	Case Western Reserve University, MD
1998-1999	Intern, Internal Medicine, University of Pennsylvania
1999-2001	Resident, Internal Medicine, University of Pennsylvania
2001-2003	Robert Wood Johnson Clinical Scholar, University of Chicago
2002-2003	University of Chicago, Department of Health Studies, MS

Medical Licensure

Drug Enforcement Agency Controlled Substance Licensure, through 6/30/21
Maryland Physician and Controlled Substance License, through 6/30/18

Medical Board Certification

American Board of Internal Medicine, through 2021

PROFESSIONAL EXPERIENCE

2014-	Affiliate Faculty, Center for Health Services and Outcomes Research (CHSOR), Johns Hopkins University
2012-	Associate Professor of Epidemiology and Medicine, Johns Hopkins Bloomberg School of Public Health

2012-	Founding Co-Director, Johns Hopkins Center for Drug Safety and Effectiveness
2011-2012	Associate Professor, Division of General Medicine, University of Chicago
2007-2012	Affiliate Faculty, Center for Interdisciplinary Health Disparities Research (CIHDR), University of Chicago
2005-	Adjunct Research Associate, Department of Pharmacy Practice, University of Illinois at Chicago School of Pharmacy
2005-2011	Assistant Professor, Division of General Medicine, University of Chicago
2003-2005	Instructor, Division of General Medicine, University of Chicago
2003-2006	Affiliate Faculty, Robert Wood Johnson Clinical Scholars Program
2003-2012	Affiliate Faculty, MacLean Center for Clinical Medical Ethics
2001-2003	Off-tour Attending Physician, Veterans Affairs Hospital, Hines, Illinois

PROFESSIONAL ACTIVITIES

Society Membership and Leadership

1998-2001	Philadelphia County Medical Society
1998-2009	American Medical Association
1998-	Physicians for Social Responsibility
1998-	Alpha Omega Alpha Medical Honors Society
2000-	Society for General Internal Medicine
2000-	American College of Physicians
2003-2009	American Society of Bioethics and Humanities
2006-2007	Chair, Program Committee, RWJ Faculty Scholars National Meeting
2006	Member, Program Committee, RWJ Faculty Scholars National Meeting
2007-	International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
2008	Selection Committee, Midcareer Research Mentorship Award, SGIM
2009-	International Society for Pharmacoepidemiology (ISPE)

Non-Commercial Advisory Boards

2000-2003	Transplant Task Force, End Stage Renal Disease Renal Network #9/#10
2005	American Society of Bioethics and Humanities President's Advisory Committee on Ethics Standards
2007-2011	Cost of Cancer Care Task Force, American Society of Clinical Oncology
2008-2016	Charter Member, IMS Health Services Research Network
2010-2014	FDA, Drug Safety and Risk Management Advisory Committees, Ad Hoc Member <ul style="list-style-type: none"> • October 2010 Cardiovascular and Renal Committee (Darbapoeitin) • October 2012 Endocrinologic and Metabolic Committee (lomitapide/mipomersen) • July 2013 Arthritis Committee (Criteria for axial spondyloarthritis) • November 2013 Peripheral & Central Nervous System Committee (Alemtuzumab) • May 2014 Public Meeting (Post Marketing Requirements for Opioid Analgesics) • July 2015 Bone, Reproductive and Urologic Drugs Committee (Flibanserin) • December 2015 Pulmonary & Allergy Drugs Committee (Cough Syrup/Codeine) • October 2016 Bone, Reproductive and Urologic Drugs Committee (desmopressin) • November 2017 Psychopharmacologic Drugs Advisory Committee (buprenorphine)
6/2014-	Chairman, FDA Peripheral and Central Nervous System Drugs Advisory Committee <ul style="list-style-type: none"> • November 2015 Peripheral & Central Nervous System Committee (Drisapersen) • April 2016 Peripheral & Central Nervous System Committee (Eterplirsen) • April 2018 Peripheral & Central Nervous System Committee (Cannabidiol)
8/2015-7/2018	Center of Excellence for Comparative Effectiveness, University of Illinois at Chicago

2015-2017 Legal Science, LLC, contract through National Institutes of Drug Abuse to develop Prescription Drug Abuse Policy System
 2016- Scientific Advisory Board, Media Policy Center, Santa Monica, California
 2/2016 Facilitator, Prioritizing Comparative Effectiveness Research Questions for Preventing Opioid Misuse in the Management of Pain: A Stakeholder Workshop (PCORI)

Commercial Advisory Boards

1/2007- IQVIA Institute for Healthcare Informatics
 1/2014-6/2016 PainNavigator, LLC, Minneapolis, Minnesota
 10/2015- Delta Faucet Company, Indianapolis, Indiana
 7/2016-6/2018 MesaRx Innovations, New York, New York
 1/2017- OptumRX National P&T Committee

Other Commercialization Activity

8/2017- Co-Founder, Monument Analytics, A Health Care Consultancy

Testimony and Briefings

2012 Food and Drug Administration (Drug Labeling for Prescription Opioids)
 2015 U.S. Senate Veterans' Affairs Committee (Prescription Opioids)
 2016 Centers for Disease Control and Prevention (Prescription Opioids)
 2016 Committee on Health and Government Operations, Maryland House of Delegates (Prescription Drug Monitoring Programs)
 2016 Food and Drug Administration (Prescription Opioids)
 2016 National Academy of Sciences, Institute of Medicine (Regulation of Opioids)
 2017 Senate Finance Committee, Maryland House of Delegates (Prescription Drug Pricing)
 2017 U.S. House of Representatives, Congressional Oversight Committee (Opioid Epidemic)
 2018 Briefing for U.S. Senate Staff Hosted by Senator Ben Cardin (Opioid Epidemic)
 2018 National Academy of Science, Engineering and Medicine (Opioid Epidemic)
 2019 Maryland House of Delegates (Prescription Drug Monitoring Program)

EDITORIAL ACTIVITIES

Peer Review Activities

Ad hoc reviewer – Journals

American Journal of Kidney Diseases	Health Services Research
American Journal of Managed Care	Hypertension
American Journal of Medicine	International Journal of Quality Improvement
American Journal of Preventive Medicine	JAMA
American Journal of Public Health	Journal of American College Health
Annals of Internal Medicine	Journal of the American Pharmacists Association
Archives of Internal Medicine	Journal of the American Society of Nephrology
BioMed Central (BMC) Gastroenterology	Journal of Clinical Ethics
BioMed Central (BMC) Infectious Diseases	Journal of General Internal Medicine
British Journal of Cancer	Journal of Rural Health
British Medical Journal	Medical Care
Canadian Medical Association Journal	Medical Decision Making
Clinical Therapeutics	Milbank Quarterly
CNS Drugs	New England Journal of Medicine
Disease Management and Health Outcomes	PharmacoEconomics
Drugs	Pharmacoepidemiology and Drug Safety
Health Affairs	Social Science and Medicine

Editorial Board Memberships

2007-2010	Medical Decision Making, Deputy Editor
2008-2012	Journal of General Internal Medicine, Deputy Editor
2008-2010	Society of General Internal Medicine Forum, Associate Editor
2010-2011	BMC Health Services Research, Associate Editor
2012-2014	Journal of the American Pharmacists Association (JAPhA), Editorial Board
2012-2014	Journal of General Internal Medicine, Editorial Board
2012-	Medical Care, Deputy Editor
2013-	Drug Safety, Editorial Board
2014-	Drugs – Real World Outcomes, Editorial Board

Grant Reviews

1. The Netherlands Organization for Health Research and Development (ZonMw), The Ministry of Health, Welfare, and Sport, The Hague, The Netherlands (2007)
2. The University of Chicago Program for Pharmaceutical Policy (2007-2010)
3. University of Chicago/University of Illinois at Chicago CDC Center for Health Promotion Economics (2007)
4. The University of Chicago Diabetes Research and Training Center (2008).
5. Agency for Healthcare Research and Quality, Special Emphasis Panel (R18), “Optimizing Prevention and Healthcare Management for the Complex Patient.” March 2008.
6. RFA 09-003. NIH Challenge Grants in Health and Science Research (RC21). April 2009.
7. National Institute of Aging Special Emphasis Panel (PO1). Medical Professionalism and Healthcare Grants. November 2009.
8. Agency for Healthcare Research and Quality Special Emphasis Panel (R18). Comparative Effectiveness Delivery System Demonstration Grants. July 2010.
9. Agency for Healthcare Research and Quality. Centers for Education and Research in Therapeutics (CERT) (U-19) Special Emphasis Panel. July 2011.
10. Swiss National Science Foundation. Drug Lag in Switzerland: Does it Exist and Why? June 2012.
11. Dutch Ministry of Health Grant Review. Optimizing the use of Over-the-Counter Medicines. October 2012.
12. Qatar National Research Fund Reviewer. November 2012.
13. Veterans Health Affairs Health Services Research and Development (HSR&D) Center of Innovation Review. February 2012.
14. Ad hoc reviewer. Agency for Healthcare Research and Quality. Health Care Research Training (HCRT) Study Section. January 2014 – July 2015.

15. Ad hoc reviewer. Canadian Institutes of Health Research (CIHR). Review Committee for the Drug Safety and Effectiveness Network (DSEN) and the Strategy for Patient-Oriented Research (SPOR) Catalyst Grant: Methods in Post-Market Drug Safety and Effectiveness Research. January 2015.
16. Study section member. Agency for Healthcare Research and Quality. Health Care Research Training (HCRT) Study Section. August 2015 – July 2018.
17. Chairman. Patient Centered Outcomes Research Institute. Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain Merit Review. May 2016.
18. Chairman. Patient Centered Outcomes Research Institute. Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain Merit Review. May 2017.
19. Chairman. Patient Centered Outcomes Research Institute. Assessment of Prevention, Diagnosis, and Treatment Options (APDTO) Program. August 2017.

HONORS AND AWARDS

Honors

- | | |
|-----------|---|
| 1993 | Cum Laude, University of Pennsylvania |
| 1997 | Alpha Omega Alpha, Case Western Reserve University |
| 2003-2005 | John A. Oremus Memorial Scholar (\$40,000 Research Stipend), MacLean Center for Medical Ethics, University of Chicago |
| 2006 | Top 5% of reviewers, Medical Care (also received annually through 2011) |
| 2007 | Top 10% of reviewers, Ann Intern Med (also received 2008, 2009, 2014) |
| 2011 | Elected Fellow of the American College of Physicians (FACP) |
| 2011 | Top Reviewers, Pharmacoepidemiology and Drug Safety (annually through 2014) |

Awards

- | | |
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| 2001 | Edward W. Holmes Resident Research Award, University of Pennsylvania |
| 2006-2009 | Robert Wood Johnson Foundation Faculty Scholar Career Development Award |
| 2007 | Research Finalist, International Society for Pharmacoeconomics and Outcomes Research, Annual Meeting |
| 2008 | Outstanding Physician Scientist Award, Central Society for Clinical Research |
| 2008 | Career development award (\$10,000 Research Stipend), Central Society for Clinical Research |
| 2008 | Department of Medicine Research Award (awarded to trainee for mentored research; also received by mentored trainees in 2009 and 2010) |
| 2009 | Pritzker School of Medicine Sigma Xi Award for Impact on Science (awarded to trainee for mentored research) |
| 2017 | Americal Society of Health-System Pharmacy, Drug Therapy Research Award (awarded to trainee for mentored research and cv publication #144) |

PUBLICATIONS

Peer Reviewed Journal Articles (names of trainees are underlined)

1. Szele F, **Alexander GC**, Chesselet MF. "Expression of molecules associated with neuronal plasticity in the striatum after aspiration versus thermocoagulatory lesions in the adult cortex in adult rats." *Journal of Neuroscience*. 1995;15:4429-4448. PMID: 7790918
2. **Alexander GC**, Fera B, Ellis R. "From the students: learning continuous improvement by doing it." *Joint Commission Journal on Quality Improvement*. 1996;22:198-205. PMID: 8664952
3. **Alexander GC**, Sehgal AR. Dialysis patient assessments of the quality of medical care provided by generalists, nephrologists and other specialists. *American Journal of Kidney Disease*. 1998;32:284-289. PMID: 9708614
4. **Alexander GC**, Sehgal AR. Barriers to cadaveric renal transplantation among blacks, women, and the poor. *JAMA*. 1998;280:1148-1152. PMID: 9777814
 Editorial: Milford EL. Organ transplantation--barriers, outcomes, and evolving policies. *JAMA*. 1998;280:1184-1185. PMID: 9777820
5. Lewin L, Agneberg B, **Alexander GC**. A course in end-of-life care for third year medical students. *Academic Medicine*. 2000;57:519-520. PMID: 10824792
6. **Alexander GC**, Sehgal AR. Why hemodialysis patients fail to complete the transplant process. *American Journal of Kidney Disease*. 2001;37:321-328. PMID: 11157373
 Editorial: Chertow GM, Zenios SA. Gridlock on the road to kidney transplantation. *American Journal of Kidney Disease*. 2001;37:435-437. PMID: 11157389
7. Werner RM, **Alexander GC**, Fagerlin A, Ubel PA. The "hassle factor": How physicians respond when third party payers decline reimbursement for important health care services. *Archives of Internal Medicine*. 2002;162:1134-1139. PMID: 12020183
8. **Alexander GC**, Sehgal AS. Variation in access to kidney transplantation across dialysis facilities: using process of care measures for quality improvement. *American Journal of Kidney Disease*. 2002;40:824-831. PMID: 12324919
 Editorial: Powe NR, Boulware LE. The uneven distribution of kidney transplants: getting at the root causes and improving care. *American Journal of Kidney Disease*. 2002;40:861-863. PMID: 12324926
9. **Alexander GC**, Werner RM, Fagerlin A, Ubel PA. Public support for physician deception of insurance companies. *Annals of Internal Medicine*. 2003;138:472-475. PMID: 12639080
10. **Alexander GC**, Wynia MK. Ready and willing? Physicians' sense of preparedness for bioterrorism. *Health Affairs*. September/October 2003;22:189-197. PMID: 14515895
11. **Alexander GC**, Casalino LP, Meltzer DO. Patient-physician communication about out-of-pocket costs. *JAMA*. 2003;290:953-958. PMID: 12928475
12. **Alexander GC**, Werner RM, Ubel PA. The costs of denying scarcity. *Archives of Internal Medicine*. 2004;164:593-596. PMID: 15037486

13. **Alexander GC**, Casalino LP, Tseng CW, McFadden D, Meltzer DO. Barriers to patient-physician communication about out-of-pocket costs. *Journal of General Internal Medicine*. 2004;19:856-860. PMID: PMC1492500
14. **Alexander GC**, Tseng CW. Strategies to identify and assist patients burdened by out-of-pocket prescription costs. *Cleveland Clinic Journal of Medicine*. 2004;71:433-437. PMID: 15195778
15. Werner RM, **Alexander GC**, Fagerlin A, Ubel PA. Lying to insurance companies: the desire to deceive among physicians and the public. *American Journal of Bioethics*. 2004;4:1-7. PMID: 16192208
16. Dai C, Stafford RS, **Alexander GC**. National trends in Cox-2 inhibitor use since market release: non-selective diffusion of a selectively cost-effective innovation. *Archives of Internal Medicine*. 2005;165:171-177. PMID 15668363

Editorial: Solomon DH, Avorn J. Coxibs, science, and the public trust. *Archives of Internal Medicine*. 2005;165:158-160. PMID: 15668360
17. **Alexander GC**, Casalino LP, Metlzer DO. Physician strategies to reduce patients' out-of-pocket prescription costs. *Archives of Internal Medicine*. 2005;165:633-636. PMID: 15795338
18. Buss MK, **Alexander GC**, Switzer GE, Arnold RM. Assessing competence of residents to discuss end-of-life issues with patients. *Journal of Palliative Medicine*. 2005;8:363-371. PMID: 15890047
19. Lang P, Schwarze M, **Alexander GC**. New technologies meeting old professional boundaries: the emergence of carotid artery stenting. *Journal of the American College of Surgery*. 2005;200:854-860. PMID: 15922195
20. **Alexander GC**, Mohajir N, Meltzer DO. Consumers' perceptions about risk of and access to nonprescription medications. *J Am Pharm Assoc*. 2005;45:363-70. PMID: 15991758
21. Wang YR, **Alexander GC**, Meltzer DO. Lack of effect of guideline changes on LDL cholesterol reporting and control for diabetes visits in the U.S., 1995-2004. *Diabetes Care*. 2005;28:2942-4. PMID: 16306559
22. **Alexander GC**, Kurlander J, Wynia MK. Physicians in retainer ("concierge") practice: a national survey of physician, patient, and practice characteristics. *Journal of General Internal Medicine*. 2005;20:1079-83. PMID: PMC1490281
23. **Alexander GC**, Lantos J. The doctor-patient relationship in the post-managed care era. *American Journal of Bioethics*. 2006;6:29-32. PMID: 16423784
24. Wang YR, **Alexander GC**, Meltzer DO. Screening and use of cholesterol-lowering drug therapy for primary and secondary prevention of coronary heart disease, 1999 and 2003. *Managed Care Interface*. 2006;19:25-30. PMID: 16453992
25. Piette J, Heisler M, Horne R, **Alexander GC**. A conceptually-based approach to understanding chronically-ill patients' responses to medication cost pressures. *Social science and medicine*. 2006;62:846-857. PMID: 16095789
26. Holmes HM, Cox-Hayley DM, **Alexander GC**, Sachs GA. Reconsidering medication appropriateness for patients late in life. *Archives of Internal Medicine*. 2006;166:605-609. PMID: 16567597

27. Schwarze ML, Sayla MA, **Alexander GC**. Exploring patient preferences for infrainguinal bypass surgery. *Journal of the American College of Surgery*. 2006;202:445-452. PMID: 16500249
28. **Alexander GC**, Delisser HM, Hansen-Flaschen J, Lantos J. Shoring up professionalism: building upon disagreements between house officers and attending physicians. *Canadian Family Physician*. 2006;52:286-287. PMCID: PMC1479701
29. **Alexander GC**, Sayla MA, Holmes HM, Sachs GA. Prioritizing and stopping prescription medicines. *Canadian Medical Association Journal*. 2006;174:1083-1084. PMCID: PMC1421477
30. **Alexander GC**, Hall M, Lantos J. Rethinking professional ethics in the cost-sharing era. *American Journal of Bioethics*. 2006;6:W17-W22. PMID: 16885085
31. Federman AD, **Alexander GC**, Shrank WH. Simplifying the Medicare Prescription Drug Benefit for physicians and patients. *Mayo Clinic Proceedings*. 2006;81:1217-1221. PMID: 16970218
32. Quinn MT, **Alexander GC**, Hollingsworth D, O'Connor KG, Meltzer DO, for the Corporate Contributions for Life Consortium. Design and evaluation of a workplace intervention to promote organ donation. *Progress in Transplantation*. 2006;16:253-259. PMID: 17007162
33. Colker TR, Casalino LP, **Alexander GC**, Lantos J. Should our well-child care system be redesigned? A national survey of pediatricians. *Pediatrics*. 2006;118:1852-1857. PMID: 17079554
34. **Alexander GC**, Larkin G, Wynia MK. Preparedness for bioterror and competing public health priorities: a national survey of primary care and emergency physicians. *Academic Emergency Medicine*. 2006;13:1238-1241. PMID: 16614456
35. Wang YR, **Alexander GC**, Stafford RS. Outpatient treatment and control of hypertension in Western Europe and the United States. *Archives of Internal Medicine*. 2007;167:141-147. PMID: 17242314
36. Schwarze ML, Sayla MA, **Alexander GC**. A comparison of patient and physician beliefs about infrainguinal bypass surgery: what role should surgical optimism play? *Surgery*. 2007;141:239-244. PMID: 17263981
37. Casalino LP, **Alexander GC**, Jin L, Konetzka T. General internists' views on pay-for-performance and public reporting of quality scores: a national survey. *Health Affairs*. 2007;26:492-499. PMID: 17339678
38. Pham HH, **Alexander GC**, O'Malley AS. Physician consideration of patients' out-of-pocket costs in making common clinical decisions. *Archives of Internal Medicine*. 2007;167:663-668. PMID: 17420424
39. Torke A, **Alexander GC**, Lantos J, Siegler M. The doctor-surrogate relationship. *Archives of Internal Medicine*. 2007;167:1117-1121. PMID: 17563018
40. Kuwabara SA, Van Voorhees BW, Gollan JK, **Alexander GC**. A qualitative exploration of depression in emerging adulthood. *General hospital psychiatry*. 2007;29:317-324. PMCID: PMC2769013

41. Tseng CW, Brook RH, Keeler E, Steers WN, **Alexander GC**, Waitzfelder BE, Mangione CM. Elderly patients' preferences and experiences with providers in managing their drug costs. *Journal of the American Geriatrics Society*. 2007;55:1974-1980. PMID: 1794489
42. Phongsak SK, Wynia MK, Gadon M, **Alexander GC**. Original Communication: A Qualitative Study of Physicians' Engagement in Reducing Health Care Disparities. *Journal of the National Medical Association*. 2007;99:1315-1322. PMCID: PMC2575935
43. Yin W, Basu A, Zhang J, Rabbani A, Meltzer DO, **Alexander GC**. Impact of the Medicare Part D Prescription Drug Benefit on drug utilization and out-of-pocket expenditures. *Annals of Internal Medicine*. 2008;148:169-177. PMID: 18180465

Editorial: Stuart B. Where are the Medicare Part D claims data? *Annals of Internal Medicine*. 2008;148:1-2. PMID: 18180463
44. **Alexander GC**, Zhang J, Basu A. Characteristics of patients receiving pharmaceutical samples and association between sample receipt and out-of-pocket prescription costs. *Medical Care*. 2008;46:394-402. PMID 18362819
45. **Alexander GC**, Lin S, Sayla M, Wynia MK, Writing for the Data Committee of the Commission to End Health Care Disparities. Development of a measure of physician engagement in addressing racial and ethnic health care disparities. *Health Services Research*. 2008;43(2):773-84. PMCID: PMC2442375
46. Rabbani A, **Alexander GC**. Out-of-pocket and total costs of fixed dose combination antihypertensives and their components. *American Journal of Hypertension*. 2008;21(5):509-13. PMID: 18437141

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51. Qato DM, **Alexander GC**, Lindau ST. AAP’s Section on Integrative Medicine Suggests a More Balanced Approach to Dietary Supplement Data – In Reply. *Pediatrics*. In press.
52. Herder MR, Doshi P, Wallach JD, et al. FDA to Begin Releasing Clinical Study Reports in Pilot Programme. *BMJ*. 2018;360:k294. (letter to the editor)
53. Mudumbai S, Stafford RS, **Alexander GC**. Having Surgery? Beware of Risk from Post-Op Opioids. *USA Today*. February 12, 2019. (Op-Ed)

Monographs, book chapters and other scientific reports

1. **Alexander GC**, Wynia MK. Survey research in bioethics. In “Empiric Methods for Bioethics: A Primer.” Eds: Jacoby L, Siminoff LA. Elsevier Press, New York, New York, 2007”.
2. Quinn MT, Gnepp J, **Alexander GC**, Hollingsworth D, O’Connor KG, Lang W, Klayman J, Meltzer DO. Design and Evaluation of Worksite Promotions of Organ Donation: Real-world Challenges and Practical Solutions. In “Understanding organ donation: applied behavioral science perspectives.” Eds: Siegel JT, Alvaro EM. Blackwell/Claremont Applied Social Psychology Series. Wiley-Blackwell, Chichester, West Sussex, United Kingdom, 2010.
3. Saunders M, **Alexander GC**, Siegler M. Clinical ethics and the practice of hospital medicine. In “Principles and Practice of Hospital Medicine.” Eds: McKean, Ross, Dressler, Brotman, Ginsberg. McGraw-Hill Companies, 2012 (2nd Edition printed 2016).
4. **Alexander GC**, Frattaroli S, Gielen AC, eds. The Prescription Opioid Epidemic: An Evidence-Based Approach. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015
5. Citizen Petition to the Food and Drug Administration (Signatory). Requesting that the Commission to the FDA place a black box warning on pharmaceuticals in the opioid and benzodiazepine classes warning patients of the potential serious risks with concomitant use of both classes of medications. Submitted February 22, 2016. Petition granted August 31, 2016. Petition available at: [http://health.baltimorecity.gov/sites/default/files/Final%20Draft%20FDA%20petition-Full%20Co-Signers-2.19.16%20\(2\)%20\(1\).pdf](http://health.baltimorecity.gov/sites/default/files/Final%20Draft%20FDA%20petition-Full%20Co-Signers-2.19.16%20(2)%20(1).pdf) (Accessed September 1, 2016).
6. Working Group Member. Transparency at the U.S. Food and Drug Administration: Recommendations to Support the Development of Safe and Effective Medical Products. October 2016.
7. Working Group Member. Partnership Forum: Navigating Innovations in Diabetes Care. Journal of Managed Care and Specialty Pharmacy. December 2016.
8. Sharfstein JM, Miller JD, Davis AL, Ross JS, McCarthy ME, Smith B, Chaudhry A, Alexander GC, Kesselheim AS. Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products. January 22, 2017.
9. **Alexander GC**, Frattaroli S, Gielen AC, eds. The Opioid Epidemic: From Evidence to Impact. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2017.
10. Bicket MC, **Alexander GC**. Physician Prescribing Guidelines and Improving Opioid Stewardship. In “The Public Health Guide to Ending the Opioid Epidemic.” In press.

Other

Designed and hosted a web site devoted to patient education and empowerment regarding prescription costs and polypharmacy. Previously available (2005-2012) at: <http://prescriptions.bsd.uchicago.edu/>

CURRICULUM VITAE
G. Caleb Alexander, MD, MS

PART II

TEACHING (Johns Hopkins University, 2012-present)

Graduate students (iMPH or MPH Advisor)

- Vibhuti Arya, PharmD; Academic Advisor for Part-time iMPH Program, 2012-2016
- Haley Gibbs, PharmD; Academic Advisor for Part-time iMPH Program, 2012-2015
- Ayu Katada; Academic Advisor for MPH Program (MPA/MBA Dual Degree), 2012-2014
- Etka Argawal; Academic Advisor for MPH Program in Epidemiologic and Biostatistical Methods for Public Health and Clinical Research, 2013-2014
- Lee Meller, MD; Academic Advisor for Part-time iMPH Program, 2013-2014
- Sharonjit Sagoo, PharmD; Academic Advisor for Part-time iMPH Program, 2015-
- Carolyn Tieu, PharmD, Academic Advisor for MPH Program, 2016-2017
- Ken Ogasawara, PhD, Academic Advisor for MPH Program, 2016-2017
- Denise Lepley, Academic Advisor for Part-time iMPH Program, 2017-2018
- Varsha Lalchandani, Academic Advisor for Part-time iMPH Program, 2018-2019
- Juan Franco, MD, Academic Advisor for Part-time iMPH Program, 2018-2019

Graduate students (MHS Advisor)

- Francine Chingcuanco; Academic Advisor for MHS Program in Cardiovascular Epidemiology, 2014-2016
- Geetha Ayer; Academic Advisor for ScD Program in Cardiovascular Epidemiology, 2014-2016
- Meijia Zhou; Academic Advisor for MHS Program in General Epidemiology and Methodology, 2012-2014
- Jeffrey Yu; Academic Advisor for MHS Program in Health Economics, 2017-2018
- Hanzhe Shang; Academic Advisor for MHS Program in General Epidemiology and Methodology, 2017-2019

Graduate students (Capstone or Thesis Advisor)

- Ayu Katada; Academic Advisor for MPH Program (MPA/MBA Dual Degree), 2012-2014
- Jinhee Moon, MHS; Capstone Advisor for MPH Program, 2012-2013 (Outstanding Achievement Award)
- Steven Jones; Capstone Advisor for MPH Program, 2012-2013
- David Nartey; Capstone Advisor for MPH Program, 2012-2013
- Tatyana Lyapustina; Capstone Advisor for MPH Program (MD/MPH Dual Degree), 2014-2015
- James Goldberg; Capstone Advisor for iMPH Program, 2015-2016
- Zoya Fansler; Capstone Advisor for Part-time iMPH Program, 2015-2016
- Jeong Ah Cho; Capstone Advisor for MPH Program (MPH/MBA Dual Degree), 2016-2018
- Shengyuan (David) Luo; Thesis Co-Advisor for MHS Program, 2016-2018
- Yunwen Xu; Thesis Advisor for MHS Program, 2016-2018
- Omar Mansour; Thesis Advisor for MHS Program, 2016-2018
- Jeffrey Rollman; Capstone Advisor for MPH Program, 2017-2018
- Nune Makarova; Capstone Advisor for MPH Program, 2017-2018
- Nisha Parikh; Capstone Advisor for MPH Program, 2018-2019
- Xintong Li; Thesis Advisor for MHS Program, 2017-2019

Graduate Students (Doctoral Advisor or Dissertation Committee Member)

- Kevin Fain, Dissertation Committee Member (DrPH/Epidemiology), 2012-2015
- Jingwen Tan, Dissertation Committee Member (PhD/Clinical Epidemiology), 2012-2016
- Shilpa Viswanathan, Dissertation Committee Member (PhD/Clinical Epidemiology), 2012-2015
- Richard Scott Swain, Dissertation Committee Member (PhD/Clinical Epidemiology), 2013-2015
- Christopher Kaufman, Dissertation Committee Member (PhD/Mental Health), 2013-2015
- Christine Buttorff, Dissertation Committee Member (PhD/Health Policy and Management), 2012-2014
- Remington Nevin, Dissertation Committee Member (PhD/Mental Health), 2014-2017
- Mariana Socal, Dissertation Committee Member (PhD/Mental Health), 2014-2017
- Lisa Selker, Dissertation Committee Member (PhD/University of North Carolina Rollings School of Public Health), 2015-
- Sheriza Bakst, Doctoral Advisor (PhD/Epidemiology), 2015-2018
- Alex Secora, Doctoral Advisor (PhD/Epidemiology), 2016-
- Lucy Qiao, Doctoral Co-Advisor (PhD/Epidemiology), 2017-
- Kathleen Anderson, Doctoral Co-Advisor (PhD/Epidemiology), 2018-
- Jiajun Wen, Dissertation Committee Member (PhD/Epidemiology), 2018-

Other Trainees (Post-doctoral or beyond)

- Kevin Riggs, MD; Mentor for research program examining generic utilization and effect of drug coupons on drug utilization and expenditures, 2013-2016
- Mark Bicket, MD; Mentor of career development award activities focused on utilization, safety and effectiveness of prescription opioids in peri-operative setting, 2016-2018

Classroom Instruction

- Designer and Instructor, Pharmacoepidemiology: Drug Utilization, 2014-present (340.684.01)
- Co-Instructor, Design of Epidemiologic Studies: Proposal Development & Critique, 2015-present (340.715.01)
- Lecturer, Epidemiology of Aging (340.616.01)
- Lecturer, Pharmacoepidemiology Methods (340.682.01)
- Small Group Facilitator: Clinical Epidemiology, Johns Hopkins School of Medicine, 2014-2016
- Graduate Summer Institute of Epidemiology and Biostatistics: Pharmacoepidemiology (340.617.11)
 - Lecturer, 2012-2016
 - Designer and Co-Instructor, 2017-present

Other significant teaching

- Participate in informal mentoring with dozens of students through works in progress, journal clubs and seminar series within the Departments of Epidemiology (School of Public Health) and the Division of General Internal Medicine (Johns Hopkins Medicine)
- Co-lead Special Seminar Series “Pharmaceutical Safety, Value and Innovation” sponsored by Center for Drug Safety and Effectiveness

TEACHING (University of Chicago, 2001-2012)

Undergraduate students

Mounica Yanamandala, University of Chicago, Primary mentor (2009-2011)
Regina Depietro, University of Chicago, Primary mentor (2009-2011)
Mateusz Ciejska, University of Chicago, Primary mentor (2009-2010)
Sarah Gallagher, University of Chicago, Primary mentor (2008-2009)
Maliha Darugar, University of Chicago, Primary mentor (2003-2006)
Nadia Mohajir, Harris School for Public Policy, Honors thesis advisor (2002-2003)
Diane McFadden, University of Chicago, Primary mentor (2002-2003)

Graduate students

Frank Liu, Department of Pharmacy Administration, College of Pharmacy, University of Illinois at Chicago, Thesis committee (2008-2010)
Teri Arthur, PhD, MSW, Social Services Administration, Dissertation Committee (2004-2008)
Carolan Dai, PhD, Harris School of Public Policy, Dissertation Committee (2002-2007)
Sachiko Kuwabara, BA, Masters of Arts, University of Chicago (2004-2006)
Melissa Brown, BA, Masters of Arts, University of Chicago (2005-2006)

Medical students

Erica MacKenzie, BA, Research Mentor (2011)
Daniel Kozman, BA, Research Mentor (2010)
Jessica Pirella, BA, Research Mentor (2010)
Andrew Cohen, BA, Research Mentor (2009)
Michelle Stacey, BA, Research Mentor (2009)
Karen Draper, BA, Research Mentor (2008)
Allison Lale, BA, Research Mentor (2008)
Rob Guzy, MD, PhD, Residency Advisor (2007)
Susanne Phongsak, BA, Research Mentor (2006)
Cesar Guerrero, BA, Research Mentor (2006)
Patrick Lang, BA, Research Mentor (2004)
Charles Kaufmann, MD, PhD, Residency Advisor (2004-2005)
Stephanie Takahashi, MD, Residency Advisor (2005-2006)

Residents

Victoria Wong, MD, Editorial fellow, Journal of General Internal Medicine (2009-)
Femi Aboyeji, MD, Research elective mentor (2007)

Fellows

Jonas DeSouza, MD (2010-2012)
David Brush, MD (2009-2012)
Milda Saunders, MD, MPH (2008-2012)
Health services research fellows. University of Chicago (2004-2012)
MacLean Center for Clinical Medical Ethics, Lecturer (2003-2012)
Rachel Caskey, MD, Primary mentor (2006-2008)
Alexia Torke, MD, HRSA Fellow, Primary mentor (2005-2007)
Tumaini Colker, MD, MBA, Robert Wood Johnson Clinical Scholar (2005-2006)
Gretchen Schwarze, MD, MPH, Vascular Surgery (2003-2006)

Post-doctoral fellows

Dima Qato, PharmD, MPH, PhD (2011)
Atonu Rabbani, PhD (2007-2009)

Classroom Instruction

Lecturer, The doctor-patient relationship in clinical practice (2002-2011)
Lecturer, MacLean Center for Clinical Ethics Summer Intensive (2003-2011)
Designer and lecturer, Research Design Course for RWJF Clinical Scholars (2004-2006)
Designer and lecturer, Research Design Course for Fellow Summer Intensive (2004-2006)
Lecturer, Introductory Course on the fundamentals of health services research

Other significant teaching

Group leader for medical student summer research program (2004-2011)
National Youth and Leadership Forum, Faculty participant (2005-2010)
Participant in 1:1 Mentoring Program, Society of General Internal Medicine, 2007

RESEARCH GRANT AND CONTRACT PARTICIPATION

Current support

Grant: 1 T32 HL139426-01; 12/27/2017 – 12/26/2022; National Heart, Lung and Blood Institute (Alexander/Segal)

Purpose: To optimize the safe and effective use of medicines to treat heart, lung and blood diseases

Grant: R01DK115534-01A1; 8/01/18 07/31/22; National Institutes of Diabetes and Digestive and Kidney Diseases (Grams/Inker)

Purpose: To investigate the risk and benefits of specific medications across the range of kidney function within 5 large, global electronic health records

Grant: 1R01DA044987-01; 9/30/2017 – 7/31/2021; National Institutes of Drug Abuse (McGinty/Rutkow)

Purpose: To quantify the effect of state laws intended to curb high-risk opioid prescribing

Grant: 1R01DA042738-01; 02/01/17–11/30/20; National Institutes of Drug Abuse (Rutkow)

Purpose: To assess the association between clean indoor air laws, cigarette taxes, and use of smoking cessation treatments

Grant: 1 U01 FD005942-01; 9/1/2018-8/31/2022; Food and Drug Administration (Alexander)

Purpose: To enhance regulatory science through a unique FDA-academic partnership (CERSI)

Grant: 8/1/17-4/30/19; The Arnold Foundation (Andersen)

Purpose: To evaluate and advance policy recommendations to achieve a “fair price” of high cost prescription drugs

Past support (selected list)

Grant: 5/5/2017- 1/30/2018; Department of Health and Human Services/ASPE (Alexander)

Purpose: To describe the breadth and depth of coverage policies for acute and chronic back pain among a nationally representative selection of Medicaid, Medicare Advantage and commercial health plans

Grant: 7/1/2016-4/4/2017; AstraZeneca (Alexander)

Purpose: To quantify the disease burden and resource utilization associated with Systemic Lupus Erythematosus (SLE)

Grant: 12/2/2016-6/30/2017; AstraZeneca (Alexander)

Purpose: To characterize the association between organ damage, quality of life, and mortality among patients with Systemic Lupus Erythematosus (SLE)

Grant: ID# 72452; 2/15/2015-1/31/2017; Robert Wood Johnson Foundation (Rutkow)

Purpose: To understand the role of interorganizational relationships, information sharing and legally established infrastructure on prescription drug monitoring programs' function and impact within the public health system

Grant # U01FD005556: 09/15/15-08/31/16; Food and Drug Administration (Varadhan)

Purpose: To develop structural nested models to assess safety and effectiveness of generic drugs

Grant: 1 R01 HL 107345-01; 4/1/11-3/31/15; NHLBI (Alexander, Co-PI)

Purpose: To examine the effect of DTCA on prescription and non-prescription health care utilization

Grant: 1 R01 AG034187-01; 7/1/2012-6/30/2015; National Institutes on Aging (Kaestner)

Purpose: To determine if Part D Prescription Coverage Improves Health and Reduces Inpatient Use

Grant: 1 UO1 CE002499-01; 9/1/2014-9/1/2016; Center for Disease Control and Prevention (Alexander)

Purpose: To evaluate the effect of Florida's Pill-Mill Law on opioid prescribing, utilization and dispensing

Grant: ID# 24741; 7/1/2014-1/1/2016; Robert Wood Johnson Foundation (Alexander)

Purpose: To evaluate the effect of Prescription Drug Monitoring Programs on opioid prescribing, utilization and dispensing

Grant: 1 R01 HS 018960-01; 8/1/10-7/31/14; Agency for Health Care Quality and Research (Alexander)

Purpose: To assess the effect of FDA advisories on provider, patient, and firm behavior

Grant: 1 K08 HS15699-01A1; 2/01/06-2/01/11; Agency for Health Care Quality and Research (Alexander)

Purpose: To conduct a randomized trial to reduce patient's out-of-pocket prescription costs

Grant: Robert Wood Johnson Physician Faculty Scholars Award; 7/1/06-6/30/09; RWJ Foundation (Alexander)

Title: Development and evaluation of interventions to reduce patients' prescription costs

Contract: IMS Health Services Research Network; 10/1/10-12/31/11; IMS Health (Alexander)

Purpose: To develop and promote academic research network using IMS Health's data assets to address questions relevant to health care reform

Grant: UL1RR024999; 12/1/09-11/30/10; CTSA Institutional Pilot (Alexander)

Purpose: To quantify the impact of FDA advisories on psychotropic medication use among children

Grant: The University of Chicago Program for Pharmaceutical Policy; 2/01/05-6/1/09; The Merck Foundation (Meltzer)

Purpose: To foster innovative research at the University of Chicago in pharmaceutical policy with a focus on regulation, innovation, and technology assessment

Contract: HHSA 290 200 500 381; 9/16/05-9/15/10; Agency for Health Care Quality and Research (Schumock)

Title: Chicago Area Pharmaceutical Outcomes Research Consortium. Developing Evidence to Inform Decisions about Effectiveness: The DECIDE Network

Grant: The Greenwall Foundation; 7/1/10-6/30/11 (Alexander)

Purpose: To conduct a mixed-methods study to examine management of conflict between physicians and surrogates of critically ill adults

Grant: Center for Education and Research on Therapeutics (CERT); 09/01/07 – 3/31/11; Agency for Health Care Quality and Research (Meltzer)

Purpose: To create an education and research infrastructure that produces and disseminates knowledge to improve the effectiveness and cost-effectiveness of the use of therapeutics

Grant: Mixed-methods exploration of the adoption of the HPV Vaccine; 10/1/07-9/30/08; University of Chicago Program for Pharmaceutical Policy Pilot Grant (Alexander)

Purpose: To establish prevalence and determinants of HPV vaccine uptake

Contract: HHSA29020050038I; 9/15/06-1/29/07; AHRQ (Walton)

Purpose: To develop a method of prioritization of research efforts on off-label drug use

Grant: R39OT03411-01-00; 10/01/04-09/30/07; Health Resources and Services Administration Division of Transplantation (Lang)

Purpose: To develop, implement, and assess workplace intervention to increase organ donor intention

Grant: The Medicaid Pharmacy Cost Containment and Patient Outcomes; 7/1/06-6/30/07; Center for Health and the Social Sciences - University of Chicago Pilot Grant (Alexander)

Purpose: To examine association between Medicaid cost-containment policies and clinical outcomes

Grant: Donald W. Reynolds Foundation; 9/1/03-8/31/07; National Institute of Aging (Sachs)

Purpose: Faculty Development in Geriatrics

Grant: Robert Wood Johnson Foundation Clinical Scholars Program; 7/1/03-7/1/06; Robert Wood Johnson Foundation (Lantos)

Purpose: To provide a post-residency academic program that trains scholars to apply pure research methods to health-related problems.

Grant: 1 H39 OT 00086-01; 10/01/01-09/30/04; Health Resources and Services Administration Division of Transplantation (Lang)

Purpose: To develop, implement, and assess a corporate workplace intervention designed to increase intention to become an organ donor

Grant: 5 K12 AG00488; 09/01/96-08/31/04; National Institute of Aging (Sachs)

Purpose: Geriatric Academic Program Award

ACADEMIC SERVICE

2016	Faculty Search Committee (John Jackson), Department of Epidemiology, JHSPH
2015	Faculty Search Committee (Mara McAdams), Department of Epidemiology, JHSPH
2015	Faculty Search Committee, Johns Hopkins Berman Institute of Bioethics
2014-2015	Graduate Training Program in Clinical Investigation (GTPCI) Review Committee

2014-2017	Admissions and Credentials Committee, Department of Epidemiology, JHSPH
2014-	Technology Transfer Committee, JHSPH
2013-2017	Curriculum Committee, Department of Epidemiology, JHSPH
2010-2012	Diabetes Research and Training Center, University of Chicago
2006-2010	Biological Sciences Division Institutional Review Board Member
2006	Steering Committee, Conference on Pharmaceutical Policy, Chicago, Illinois
2006-2008	Steering Committee, DOM Research Day, University of Chicago
2006-2008	Steering Committee, UOC Program in Pharmaceutical Policy, University of Chicago
2005-2006	Search Committee, UOC Comprehensive Cancer Center, Population Science Director
2003-2012	MacLean Center Ethics Committee, University of Chicago
2003-2008	Medicine and the Social Sciences, Co-Chair, University of Chicago
2000-2001	General Medicine Interest Group, Co-Chair, UPHS
2000-2001	Residency Review Committee, Class Officer, UPHS
1999-2001	Hospital of the University of Pennsylvania Ethics Committee, UPHS
1996-1997	Rainbow Babies and Children's Hospital Ethics Committee, CWRU
1994-1996	Class Officer and Chair, Committee of Student Representatives, CWRU

INVITED SEMINARS

Local or Regional Seminars

1. Racial differences in access and outcomes of kidney transplantation. Workshop on medicine and the social sciences. University of Chicago. November 2002.
2. Public support for physician deception of insurance companies. Council on ethical and judicial affairs, American Medical Association. Chicago, IL. April 2003.
3. Truth and lies: are the rules different for lawyers? Panel discussion at the American Bar Association Conference on Professional Responsibility. May 2003.
4. Patient-physician communication about out-of-pocket costs. Northwestern University, December 2002.
5. Patient-physician communication about out-of-pocket costs. Program in Medicine, Arts, and the Social Sciences. University of Chicago. Feb 2004.
6. Patient-physician communication about out-of-pocket costs. Program in Medicine, Arts, and the Social Sciences. University of Chicago. February 2004.
7. Is prescription choice rational? By whose standards? Pharmaceutical innovation and regulation: an American dilemma. Faculty workshop, University of Chicago. February 2004.
8. The doctor-patient relationship in the post-managed care era. American Medical Association. Chicago, IL. May 2004.
9. National trends in Cox-2 inhibitor use since market release: the non-selective diffusion of a selectively cost-effective innovation. Center for Pharmacoeconomics Research, University of Illinois School of Pharmacy. July 2004.

10. Division of Geriatrics Grand Rounds, University of Chicago Hospitals. A framework for medication prioritization and discontinuation. December 2004.
11. Department of Medicine Grand Rounds, University of Chicago Hospitals. Pharmaceutical innovation and the doctor-patient relationship: understanding the diffusion of Cox-2 inhibitors from 30,000 feet to the ground level. February 2005.
12. Bioethics Interest Group, Stritch School of Medicine, Loyola University. Physician deception of insurance companies. April 2005.
13. Midwest Center for Health Services and Policy Research. Hines Veterans Affairs System, Hines, IL. The diffusion of pharmaceutical innovation in the Veterans Affairs Health System. November 2005.
14. American Medical Student Association Panel Discussion. Pritzker School of Medicine, University of Chicago. Discussed role of industry in physician education and prescribing. November 2005.
15. Bioethics Interest Group. Pritzker School of Medicine, University of Chicago. Empiric ethics . . . or . . . what do numbers have to do with right and wrong? February 2006.
16. Chicago Medical Society. Panel discussion on medical ethics. Holiday Inn – Chicago Mart Plaza. Chicago, IL. March 2006.
17. Ethics dinner discussion with students from Pritzker Medical School, University of Chicago, May 2006.
18. The road less traveled – career paths in general internal medicine. National Youth Leadership Forum on Medicine, Chicago, IL. June 2006.
19. The Union League. Ethics considerations in pandemic planning. Chicago, IL. October 2006.
20. Attention: You have just entered the cost-sharing era: ethical, policy, and clinical considerations. Department of Medicine Research Series, December 2006.
21. Pharmacothis and pharmacothat: exploring topics in pharmaceutical research. University of Chicago Division of General Medicine Outcomes Group. March 2007.
22. Thinking globally, acting locally: a Chicagoland collaboration to unravel the impact of the Medicare Prescription Drug Benefit. TAP Pharmaceuticals. Chicago Midwest ISPOR Meeting. April 2007.
23. What do general internists do, and why? National Youth Leadership Forum on Medicine, Chicago, IL. June 2007.
24. The best of times, the worst of times: clinical decision-making and prescription choice in the 21st Century. Department of Otolaryngology. University of Chicago. October 2007.
25. What do we know about health care provider interaction with the pharmaceutical industry? University of Illinois Medical Center at Chicago Clinical Ethics Conference. March 2008.
26. Asking the right question(s) and getting funded to do so. University of Illinois at Chicago Advanced methods and grant writing workshop. March 2008.

27. Challenges and opportunities examining the off-label use of prescription medicines. Institute for Healthcare Studies. Northwestern University, Chicago, IL, May 2008.
28. Improving pharmacotherapy during outpatient care. Primary care medicine today (PRIMED) conference. Rosemont, IL, February 2009.
29. Choosing a research question: the perennial dilemma of “what shall I study”? Midwest Hospitalist Meeting. Chicago, IL. October 2009.
30. Conflicts of interest in medicine. Pritzker School of Medicine, University of Chicago. May 2010.
31. Using social network methods to study prescription drug uptake and diffusion. Department of Health Studies. University of Chicago. November 2010.
32. Managing risk through ethical practice. ISMIE Mutual Insurance Company. Chicago, IL 2010.
33. Overview of Clinical Epidemiology, in Fundamentals of Epidemiology. Johns Hopkins Krieger School of Arts and Sciences. November 2012.
34. The Prescription Opioid Epidemic: In Search of Mission Control.
 - Johns Hopkins Welch Center for Prevention, Epidemiology and Clinical Research Grand Rounds. December 2012.
 - University of Maryland Department of Pharmaceutical Health Services Research. April 2013.
 - Johns Hopkins Department of Medicine Osler Grand Rounds, October 2013.
 - Anne Arundel Medical Center Department of Medicine Grand Rounds, January 2014.
35. Drugs and Aging, in Epidemiology of Aging. Johns Hopkins Bloomberg School of Public Health. May 2013.
36. Career Development, in Public Health Economics Seminar. Johns Hopkins Bloomberg School of Public Health. September 2013.
37. The Effect of FDA Risk Communications on Patient, Provider and Firm Behavior. Johns Hopkins Department of Psychiatry Research Conference, December 2013.
38. Managing Prescription Opioids In Workers Compensation Programs. American Insurance Association. Washington, DC. June 2014.
39. Secondary Data Analysis. General Internal Medicine Fellows Conference. Johns Hopkins Medicine. Baltimore, MD. September 2014.
40. Center for Medical Technology Policy (CMTP) Green Park Collaborative Annual Meeting. “Real World Evidence – Defining What “Good” Looks Like”. Panel Discussion. April 2015.
41. Safety, Efficacy and Pharmacokinetic Bioequivalence of Biosimilar TNF- α Inhibitors Compared with their Reference Biologics: A Systematic Review. Department of Clinical Pharmacology, Johns Hopkins Hospital. February 2016.
42. Reducing Prescription Drug Spending: A Review of Policy Options. Johns Hopkins Bloomberg School of Public Health. March 2016.

43. Keynote. Managing the Unmanageable: Reining in the Opioid Epidemic. CareFirst. Baltimore, Maryland, June 2017.
44. Moderator. Epidemiology Inclusion, Diversity, Equity & Science (Epi IDEAS) Communication with Policy Makers: The Opioid Epidemic. Panel Discussion featuring Lauren Jee and Amanda Latimore. Johns Hopkins Bloomberg School of Public Health. Baltimore, Maryland, January 2019.

National or International Seminars

45. Panel discussion of interdisciplinary health professions education. Ohio League of Nursing Annual Meeting, Cleveland, Ohio, October 1996.
46. Grand Rounds, Department of Medicine, University of Pennsylvania: Pharmaceutical industry sponsorship of continuing medical education: training physicians or marketing products? June 2001.
47. Patient-physician communication about out-of-pocket costs. University of Michigan, January 2003.
48. Patient-physician communication about out-of-pocket costs. MetroHealth Medical Center, January 2003.
49. “Luxury care”, professional standards, and personal choice: ethical and professional issues in retainer medical practices. Panel discussion at the American Society of Bioethics and Humanities Annual Meeting. October 2004.
50. Ad hoc pharmacoeconomics working group. AstraZeneca LP. Patient-physician communication about out-of-pocket costs. June 2005.
51. How much should \$38 billion buy? The uptake and impact of the Medicare Part D Prescription Benefit. Department of Medicine. VA Center for Health Equity Promotion and Research and University of Pittsburgh Department of Medicine. December 2007.
52. The Medicare Modernization Act Prescription Drug Benefit. Department of Ambulatory Care and Prevention, Harvard Medical School. January 2008.
53. Principles of survey research. Patan Academy of Health Sciences. Kathmandu, Nepal, April 2008.
54. Health care publishing in the peer-reviewed literature. Patan Academy of Health Sciences. Kathmandu, Nepal, April 2008.
55. Impact of FDA regulatory advisories on patient, provider and firm behavior. Mayo Clinic, April 2010; Virginia Commonwealth University, October 2010; Yale University, November 2010; Johns Hopkins University School of Medicine, November 2010; Johns Hopkins University School of Public Health, June 2011.
56. Special Guest: FED UP: Rally for a Federal Response to the Opioid Epidemic, National Sylvan Theater Stage at the Washington Monument, Washington DC, September 2014.
57. Panelist: Art and Science of Scientific Communications. CBI Advanstar. Publication Planning Forum. Philadelphia, PA. December 2014.

58. CMS Grand Rounds: The Opioid Epidemic. CMS Headquarters, Baltimore, MD. November 2015.
59. Panelist: Drug Safety and Surveillance. FDA/CMS Summit. IIR/IBC Life Sciences. Ritz Carlton Hotel, Washington DC, December 2015.
60. Special Guest: The Opioid Epidemic. American Insurance Association: Workers' Compensation Committee. Washington DC, February 2015.
61. Safety, Efficacy and Pharmacokinetic Bioequivalence of Biosimilar Tumor Necrosis Factor-alpha Inhibitors Compared with their Reference Biologics: A Systematic Review. Harvard Pilgrim Health Care. March 2016.
62. The Opioid Epidemic. Johns Hopkins Department of Pharmacy Grand Rounds. May 2016.
63. Guest Speaker: Innovations in Diabetes Care. Academy of Managed Care Pharmacy. Alexandria, Virginia, July 2016.
64. Panelist: Needed Changes in Federal Policy and Legislation to Address Nation's Opioid Crisis. Educational Briefing for Congressional Members and Staff. Washington, DC, September 2016.
65. Panelist: Balancing Opioid Access and Use. Academy of Managed Care Pharmacy Annual Research Symposium. Alexandria, Virginia, October 2016.
66. Keynote. An Evidence-Based Approach to the Opioid Epidemic. National Academy for State Health Policy. Pittsburgh, Pennsylvania, October 2016.
67. Special Guest Speaker. Science, Public Health and the Prescription Opioid Industry. Motley Rice LLC. Washington, DC, June 2017.
68. Guest Speaker. Opioid Prescribing Practices. Bloomberg Philanthropies. January 2018.
69. Plenary Speaker. Conundrums in Biotechnology: How Does Quality Impact Safety. World Congress of Biopharmaceuticals. Washington, DC, February 2018.
70. Special Invited Speaker. "Covering the Opioid Crisis". National Press Foundation. Washington, DC, February 2018.
71. Guest Panelist. "Addressing Prescription Drug Costs". Johns Hopkins Carey School of Business Drug Accessibility and Pricing Symposium. Baltimore, MD, March 2018.
72. Guest Panelist. "Best Practices in Opioid Prescription, Pain Management, Medicine-Assisted Treatment and Recovery: New Models of Care for Opioid Use Disorder". Modern Healthcare Opioid Symposium. Baltimore, MD, April 2018.
73. Invited Speaker. "Comparative Safety of NSAIDs and Opioids Among Hospitalized Patients: A Case Study". Premier Annual Breakthroughs Conference. Nashville, TN, June 2018.
74. Guest Speaker. National Governor's Association. Opioid Coverage Policy Roundtable. Washington, DC, June 2018.

75. Invited Panelist. National Black Caucus Foundation. Protecting the Health, Safety and Security of African American Communities. Health and Wellness Luncheon. Washington, DC, September 2018.
76. Session Moderator. State Legislative Leaders Foundation (SLLF) Fall Issues Summit. Addressing the Opioid Crisis. Baltimore, MD, September 2018.
77. Panelist. “Addiction Research – What is New and What is Interesting?” and “Why Recovery Research Matters and Why Residents and Alumni Should Participate”. Oxford House World Convention. Kansas City, MO, October 2018.
78. Facilitator. Academy of Managed Care Pharmacy Partnership Forum: “Building the Foundation for Patient-Reported Outcomes: Infrastructure and Methodologies”. Orlando, FL, November 2018.
79. Invited Panelist. National Academies of Science, Engineering and Medicine. “The Role of Nonpharmacological Approaches to Pain Management.” Washington, DC, December 2018.
80. Medicine Grand Rounds. Weill Cornell Medicine. “The Opioid Epidemic: Grief and Hope in the New Year”. New York, NY, January 2019.

NARRATIVE

G. Caleb Alexander, MD, MS is an Associate Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health, where he serves as a founding co-Director of the Center for Drug Safety and Effectiveness and Principal Investigator of the Johns Hopkins Center of Excellence in Regulatory Science and Innovation (CERSI). He is a practicing general internist and pharmacoepidemiologist and is internationally recognized for his research examining prescription drug utilization, safety and effectiveness. Dr. Alexander is the author of over 250 scientific articles and book chapters, and he has published regularly in leading scientific journals including JAMA, Health Affairs and the Annals of Internal Medicine. He is a frequent speaker on health care issues and has served on numerous editorial and advisory boards. Due to its impact and relevance to a broad sector of the general public, his work has been widely featured in a media including the Economist, Scientific American, the New York Times, the Wall Street Journal, Washington Post, National Public Radio and other media. Dr. Alexander’s research focuses on population-based patterns and determinants of pharmaceutical use, clinical decision-making regarding prescription drugs, and the impact of changes in regulatory and payment policy on pharmaceutical utilization. In addition to expertise conducting survey-based investigations, he has also extensive experience with the analysis of secondary data sources including administrative claims and large national surveys. Dr. Alexander received his B.A. cum laude from the University of Pennsylvania, an MD from Case Western Reserve University, and a Master of Science from the University of Chicago.

KEYWORDS

Pharmacoepidemiology, medication use, pharmaceutical policy, patient-physician communication, general internal medicine

Alexander Publications: 2009 - 2019

1. AMBULATORY DIAGNOSIS AND TREATMENT OF NONMALIGNANT PAIN IN THE UNITED STATES, 2000–2010 Med Care: Author manuscript; available in PMC 2014 October 01.
2. AMBULATORY DIAGNOSIS AND TREATMENT OF NONMALIGNANT PAIN IN THE UNITED STATES, 2000–2010 Med Care. 2013 October ; 51(10): .
3. Clinical Prescribing (and Off-Label Use) in a Second-Best World Medical Care. 48(4):285-287, APR 2010
4. The Effect of the Medicare Part D Prescription Benefit on Drug Utilization and Expenditures Ann Intern Med. 2008; 148:169-177.
5. EFFECTS OF PRESCRIPTION DRUG INSURANCE ON HOSPITALIZATION AND MORTALITY: EVIDENCE FROM MEDICARE PART D NBER Working Paper No. 19948 February 2014 JEL No. I12, I13,I18
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11. National Trends in Ambulatory Asthma Treatment, 1997–2009; J Gen Intern Med 26(12):1465–70.
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